



SURGICAL TECHNIQUE

PRECISION SPINE
REFORM[®]
PEDICLE SCREW SYSTEM

Standard • Reduction • HA Coated • Modular



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REFORM® PEDICLE SCREW SYSTEM OVERVIEW

Reform® is a comprehensive pedicle screw system that is designed to meet the varying requirements of degenerative, trauma and deformity procedures. Reform features a cobalt chrome tulip, a titanium triple lead proximally tapered thread and titanium and cobalt chrome rods to deliver strength, stability and efficiency to all thoracolumbar constructs. Reduction and uniplanar screw options, along with a full line of hooks, dominoes and offsets, complete the system to simplify the procedure and accommodate individual patient anatomy.

DEVICE DESCRIPTION

The Reform Pedicle Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, locking cap screws, hooks, dominoes, and lateral offsets. All of the components are available in a variety of sizes to match more closely the patient's anatomy. All components are made from medical grade stainless steel, cobalt chromium alloys, titanium or titanium alloy described by such standards as ASTM F-138, ASTM F-1537, ISO 5832-12, ASTM F-136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

The Reform HA Coated Pedicle Screws are supplied STERILE, are made from medical grade titanium or titanium alloy as described by such standards as ASTM F136 or ISO 5832-3 and feature Hydroxyapatite (HA) coating described by such standards as ISO 13779-2 and ASTM 1185-03.

INDICATIONS

The Reform Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Reform Pedicle Screw System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. The Reform Pedicle Screw System is also intended for non-cervical pedicle screw fixation (T1-S1/ilium) for the following indications: degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Reform Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Reform Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to Instructions For Use (IFU) (LBL-IFU-011) and (LBL-IFU-021; Reform HA Coated Screws) for complete system description, indications and warnings.



REFORM[®] IMPLANT FEATURES

Low Profile

- 12.72mm Footprint x 12.5mm Height
- T20 Hexalobe

Cobalt Chrome Tulip

- Reduces the Risk of “Head Splay” with DVR Maneuvers

Polyaxial Screws

- Provide 30° angulation in all planes

Proximal Tapered Thread

- Increases bone/screw interface, enhances pull-out strength

Triple Lead Thread

- Allows for efficient screw delivery

Sizing

Reform Polyaxial Screws Standard

4.5mm	25-45mm (5mm)
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-60mm (5mm), 70 & 80mm
9.5mm	60, 70 & 80mm
10.5mm*	

Reform HA Coated Polyaxial Screws Standard

5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-60mm (5mm), 70 & 80mm

Reform Uniplanar Screws

4.5mm	25-45mm (5mm)
5.5mm	25-50mm (5mm)
6.5mm	30-50mm (5mm)
7.5mm	35-50mm (5mm)

Reform Reduction Screws

4.5mm*	
5.5mm	30-50mm (5mm)
6.5mm	30-50mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-55mm (5mm)
9.5mm*	
10.5mm*	

Reform Reduction Uniplanar Screws

5.5mm	25-50mm (5mm)
6.5mm	30-45mm (5mm)

Modular Tulips

- Standard Tulip (5.5mm)
- Reduction Tulip (5.5mm)

Modular Screws

4.5mm	25-45mm (5mm)
5.5mm	30-50mm (5mm)
6.5mm	30-55mm (5mm)
7.5mm	35-55mm (5mm)
8.5mm	40-60mm (5mm), 70 & 80mm
9.5mm	60, 70 & 80mm

* Special Order

Additional sizes available by special order, see pages 49-54.



Reform[®] Tulip Dimensions



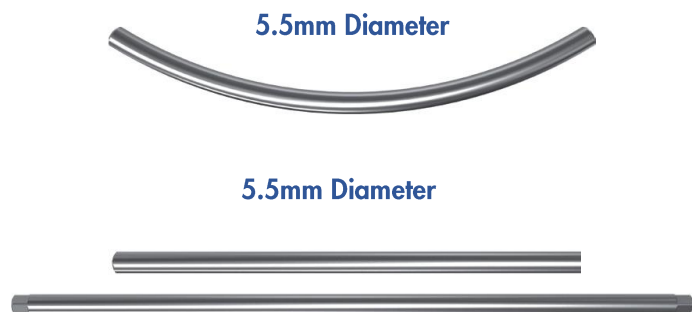
Locking Cap

- **Titanium Square Threaded Locking Cap**
 - Geometry Reduces the Risk of Cross-threading
 - Reduces Risk of Head-Splay with DVR Maneuvers
- **Hexalobular T25**
 - Reduces the Incidence of Toggle and Stripping



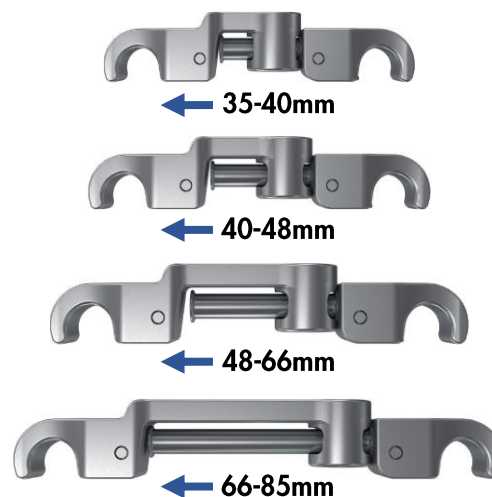
Rods

- **Titanium and Cobalt Chrome Rods**
- **Straight Rods**
 - 80mm, 100mm, 120mm, 150mm
- **Straight Hex-Ended Rods**
 - 200mm, 300mm, 400mm, 500mm
- **Lordotic "Curved" Rods**
 - 35mm-80mm (5mm increments)
 - 90mm-120mm (10mm increments)



Crosslinks

- **Adjustable**
 - 30mm (30-32mm) – Part #: 39-CC-0030*
 - 32mm (32-35mm) – Part #: 39-CC-0032*
 - 35mm (35-40mm) – Part #: 39-CC-0035
 - 40mm (40-48mm) – Part #: 39-CC-0040
 - 48mm (48-66mm) – Part #: 39-CC-0048
 - 66mm (66-85mm) – Part #: 39-CC-0066
- * Not Pictured (available in deformity add-on set)
- **Offset Cam Locking Mechanism**
- **90° Locking Motion**
- **Rod-to-Rod Connection**
- **3° of Freedom Linkage provides ±25° of Angulation**
- **T20 Hexalobe**



REFORM[®] DEFORMITY ADD-ON SYSTEM IMPLANTS

HOOKS

Various Hook options available to accommodate spine anatomy

Pedicle

- Small - Part Number: 39-TH-0101
- Medium - Part Number: 39-TH-0102
- Large - Part Number: 39-TH-0103



Straight Laminar

- Small - Narrow - Part Number: 39-TH-0201
- Small - Wide - Part Number: 39-TH-0202
- Medium - Narrow - Part Number: 39-TH-0203
- Medium - Wide - Part Number: 39-TH-0204
- Large - Narrow - Part Number: 39-TH-0205
- Large - Wide - Part Number: 39-TH-0206



Wide



Narrow

Ext.-Body Laminar (+4mm)

- Medium - Part Number: 39-TH-0212
- Large - Part Number: 39-TH-0213



Ramped Laminar

- Small - Part Number: 39-TH-0221
- Medium - Part Number: 39-TH-0222



Down Angled Laminar

- Medium - Part Number: 39-TH-0232
- Large - Part Number: 39-TH-0233



Offset Angled Laminar

- Medium - Right - Part Number: 39-TH-0301
- Medium - Left - Part Number: 39-TH-0302



Left



Right

Angled Hook

- Medium - Right - Part Number: 39-TH-0401
- Medium - Left - Part Number: 39-TH-0402



REFORM[®] DEFORMITY ADD-ON SYSTEM IMPLANTS

REDUCTION HOOKS

Straight Laminar

- Medium - Part Number: 39-TH-0242



Straight Laminar Reduction Hook

Ext.-Body Laminar (+4mm)

- Medium - Part Number: 39-TH-0252



Ext.-Body Laminar (+4mm) Reduction

Ramped Laminar

- Medium - Part Number: 39-TH-0262



Ramped Laminar Reduction Hook

Down Angled Laminar

- Medium - Part Number: 39-TH-0272



Down Angled Laminar Reduction Hook

Offset Angled Laminar

- Medium - Right - Part Number: 39-TH-0351
- Medium - Left - Part Number: 39-TH-0352



Offset Angled Laminar Reduction Hook - Right

Angled Hook

- Medium - Right - Part Number: 39-TH-0451
- Medium - Left - Part Number: 39-TH-0452



Angled Reduction Hook - Right

LATERAL OFFSETS

Closed

- 20mm - Part Number: 39-LO-0120
- 30mm - Part Number: 39-LO-0130
- 40mm - Part Number: 39-LO-0140
- 50mm - Part Number: 39-LO-0150



20mm



30mm



40mm



50mm

Closed

Top Loading

Top-Loading

- 20mm - Part Number: 39-LO-0220
- 30mm - Part Number: 39-LO-0230
- 40mm - Part Number: 39-LO-0240
- 50mm - Part Number: 39-LO-0250



20mm



30mm



40mm



50mm

REFORM[®] DEFORMITY ADD-ON SYSTEM IMPLANTS

DOMINOES

Axial

- Closed-Closed - Part Number: 39-AA-0101



Axial Domino
Closed-Closed

Parallel Domino

- Closed-Closed, Wide - Part Number: 39-DA-0101
- Closed-Closed, Narrow - Part Number: 39-DA-0102
- Closed-Open, Wide - Part Number: 39-DA-0201
- Closed-Open, Narrow - Part Number: 39-DA-0202
- Open-Open, Wide - Part Number: 39-DA-0301
- Open-Open, Narrow - Part Number: 39-DA-0302



Parallel Domino
Closed-Closed,
Wide



Parallel Domino
Closed-Closed,
Narrow

Domino Set Screw

- Part Number: 39-LS-0200



Parallel Domino
Closed-Open,
Wide



Parallel Domino
Closed-Open,
Narrow



Parallel Domino
Open-Open,
Wide



Parallel Domino
Open-Open,
Narrow

Pedicle Screw Tap

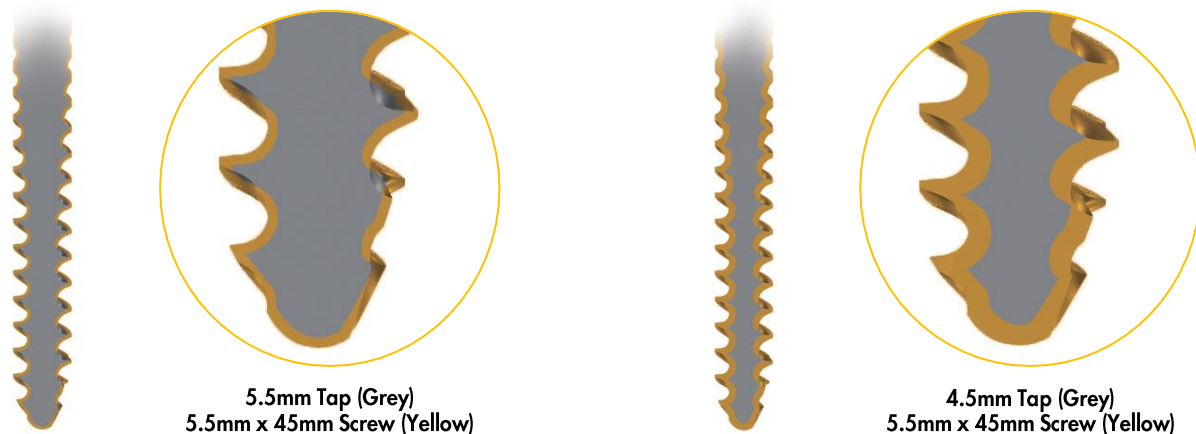
Undersized Proximally



NOTE: 10.5mm available upon request

The Reform® Pedicle Screw incorporates a proximal taper in its thread design. The difference in the diameters between the screw and tap changes as you move proximally up the thread. When comparing the 5.5mm Tap with a 5.5mm x 45mm Screw the difference in the major diameters between the Tap & Screw is .5mm (.25mm each side) and the difference between the two minor diameters is .25mm (.125mm each side) at the distal portion. At the proximal portion of the Screw thread, the difference between the major diameter of the Screw and the minor diameter of the Tap is 2mm (1mm each side). When comparing a 4.5mm Tap with a 5.5mm x 45 Screw the difference is doubled. The major/major difference is 1mm combined and the minor/minor difference is .5mm at the distal tip. At the proximal portion, the major/minor difference is 4mm.

CAUTION: Tapping to size is recommended. If hard bone is encountered, tap to size to prepare the bone for screw insertion.



HA Pedicle Screw Tap

HA Coating adds approximately **.18mm** to Major Diameter and **.25mm** to the Minor Diameter

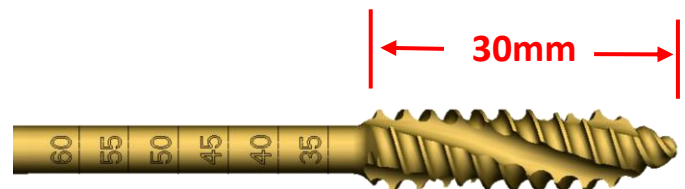


For patients with **high bone density**, the **Reform[®] HA Taps are to be used** – shown below in a Titanium Nitride coating.

For patients with poor bone density, standard Reform Taps may be used.

Reform HA Taps for HA Coated Screws:

- 0.5mm undersized on the Major Ø
- Line-to-Line on the Minor Ø



5.5mm HA Tap 39-SP-1055



6.5mm HA Tap 39-SP-1065

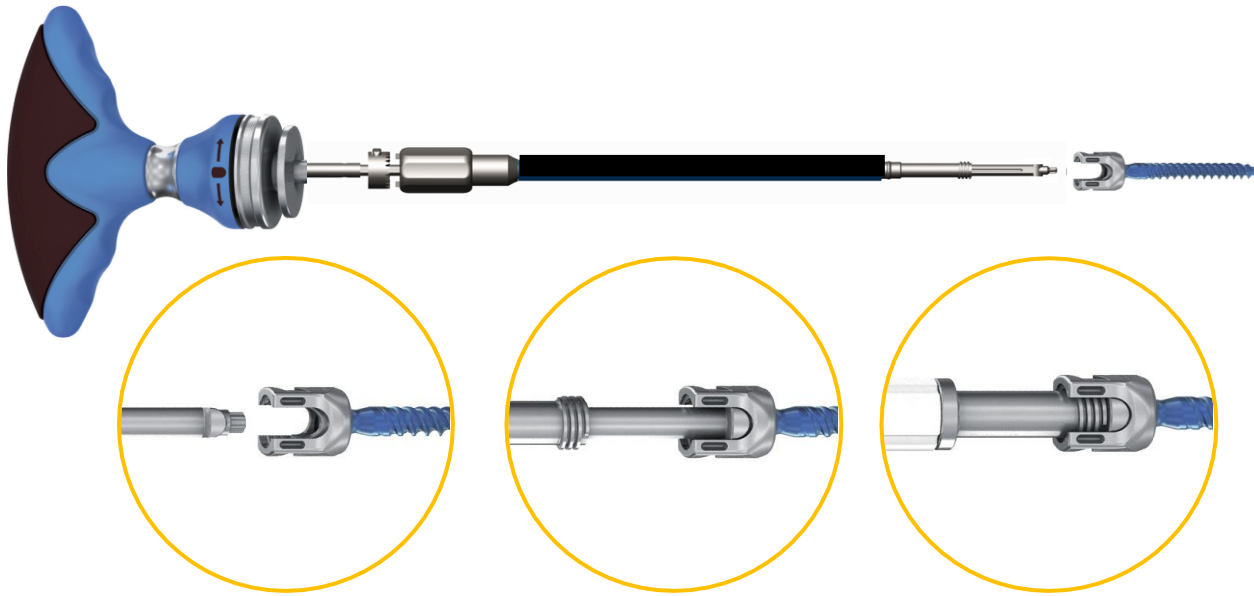


7.5mm HA Tap 39-SP-1075



8.5mm HA Tap 39-SP-1085

Pedicle Screwdriver



Bone Awl/Bone Punch

**3.6mm Diameter
15mm Length**



Ball Tip Probe (aka "Sounder")

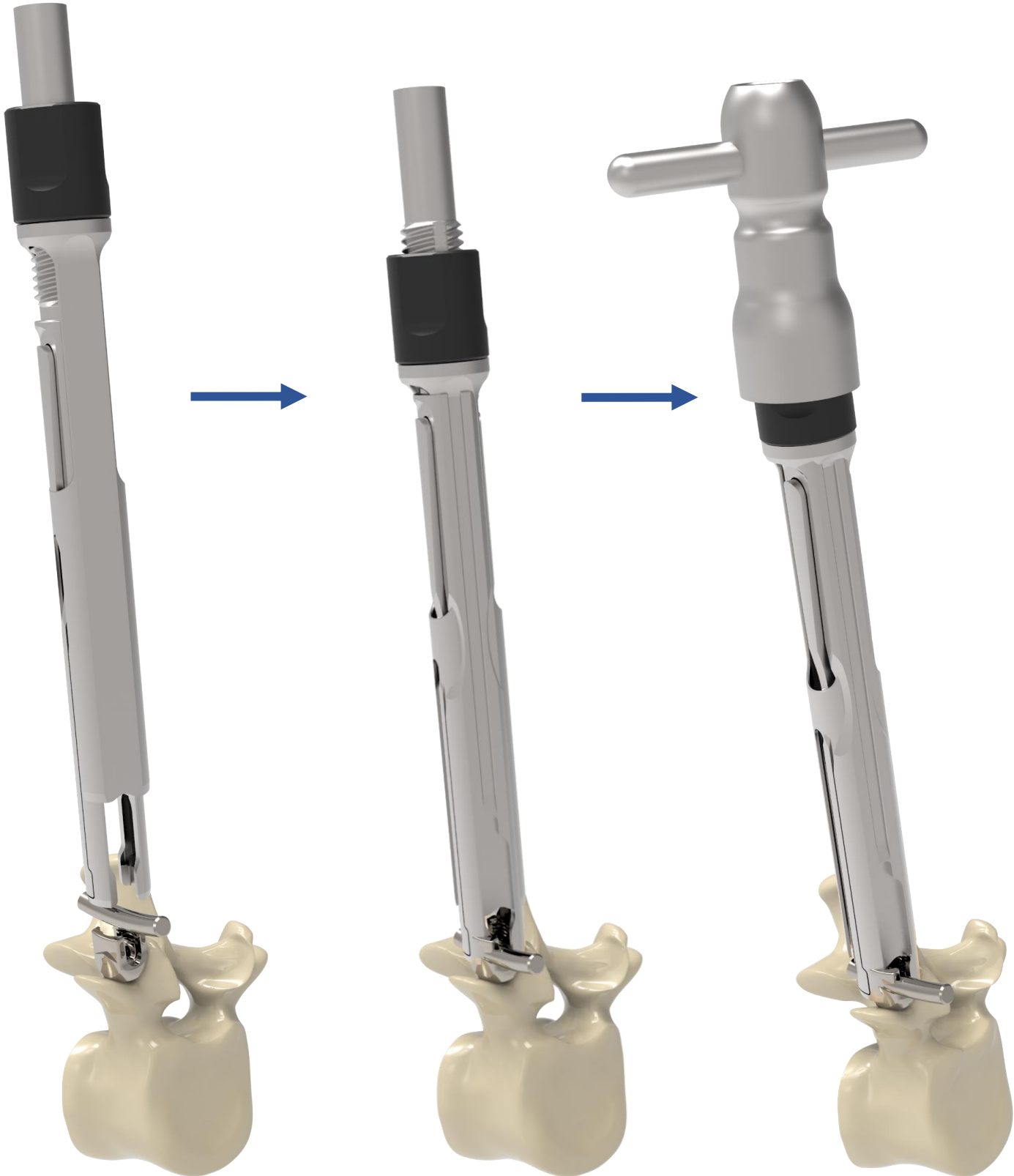
**2mm Diameter at Ball Tip
1mm Diameter above Ball Tip**



Reduction Instruments

Reduction Tower

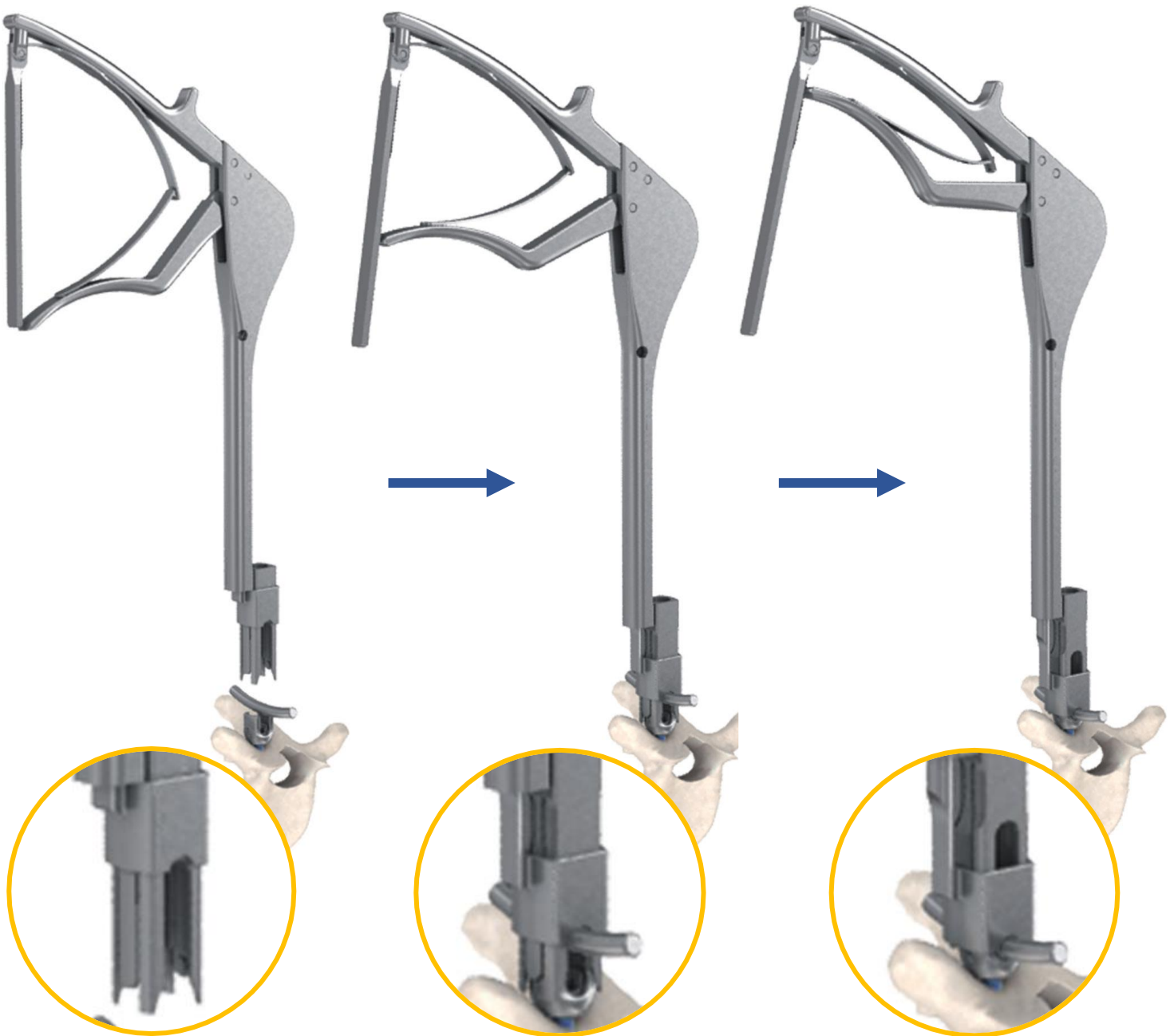
- Quick-Connect feature allows for slip-on insertion over Tulip
- 25mm of reduction capability



Reduction Instruments

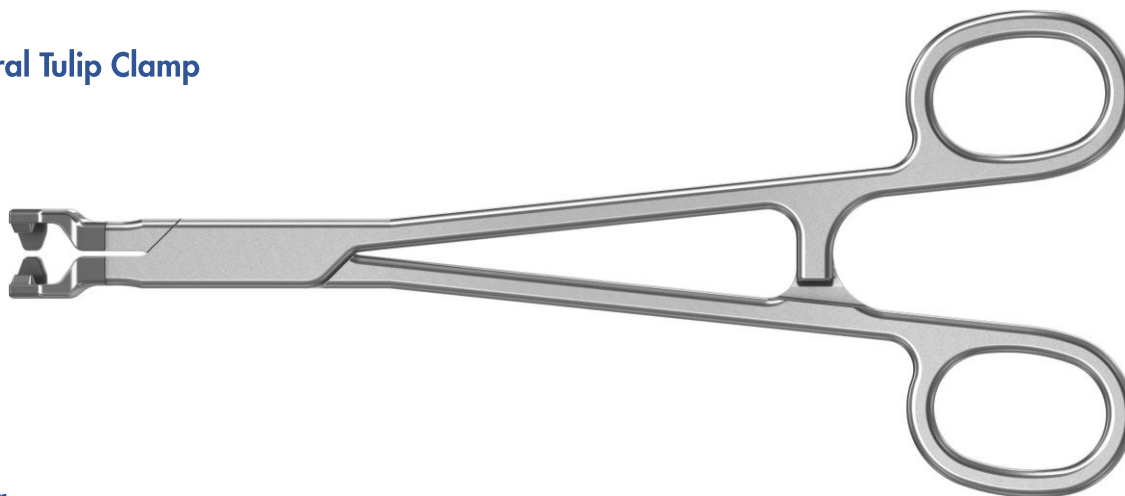
Ratcheting Reduction Gun

- Simple Finger-Squeeze Mechanism provides easy Tower release, flexing retention arms open
- 25mm of reduction capability



Reform[®] Modular Instrumentation

Angled Lateral Tulip Clamp

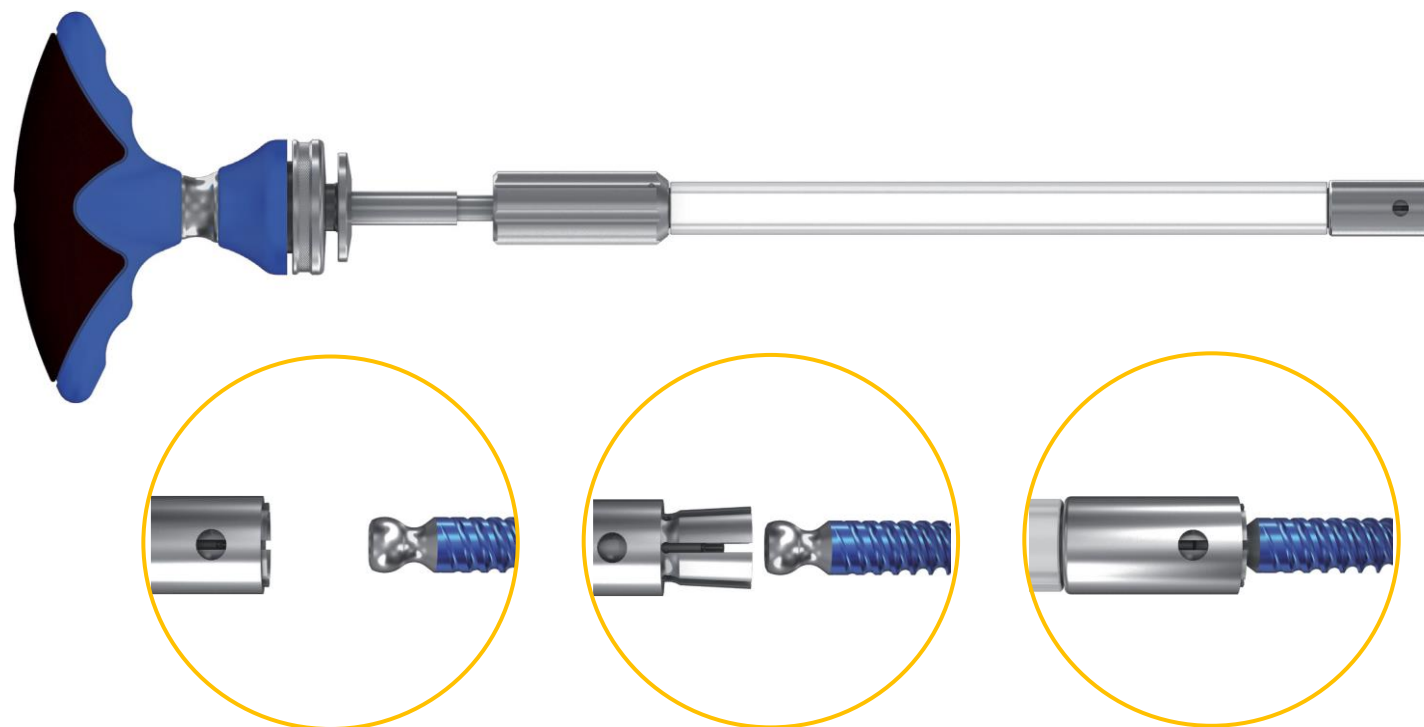


Bone Planar



Modular Screwdriver

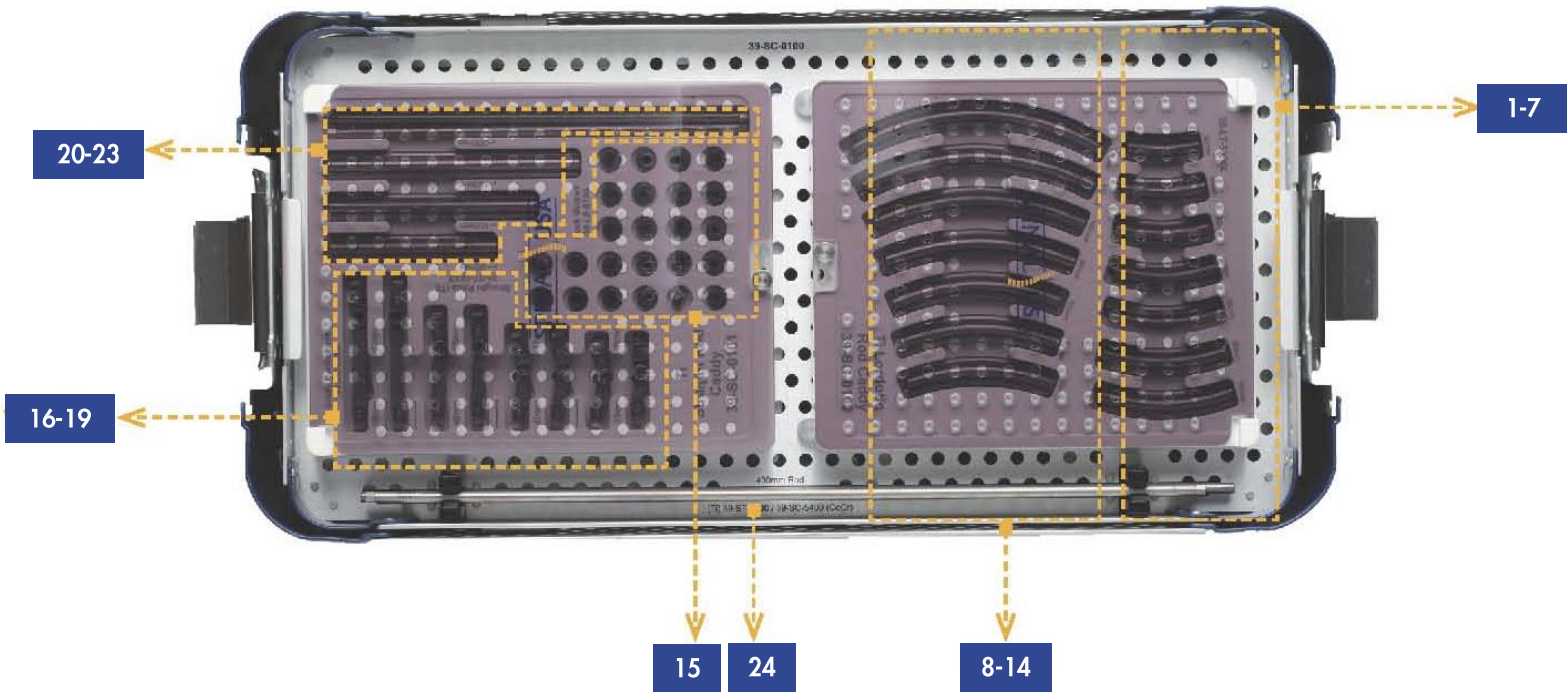
- Place screwdriver in neutral or reverse position and turn clockwise
- Turn knurled knob clockwise to tighten collet



REFORM® IMPLANT TRAY

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Top Level

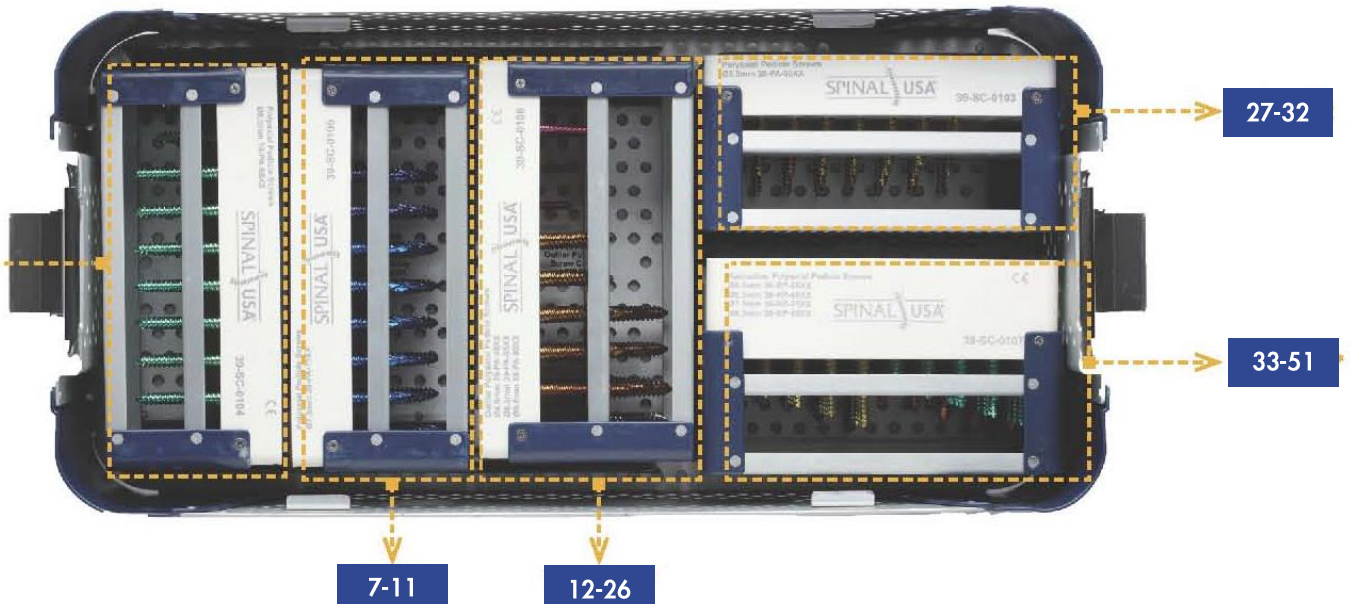


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1	39-LT-5035	Lordotic Ti Rod, 5.50 x 35mm	3	13	39-LT-5110	Lordotic Ti Rod, 5.50 x 110mm	3
2	39-LT-5040	Lordotic Ti Rod, 5.50 x 40mm	3	14	39-LT-5120	Lordotic Ti Rod, 5.50 x 120mm	3
3	39-LT-5045	Lordotic Ti Rod, 5.50 x 45mm	3	15	39-LS-0100	Cap Screw / Lock-Screw	24
4	39-LT-5050	Lordotic Ti Rod, 5.50 x 50mm	3	16	39-CC-0035	Cross Connector 35mm	2
5	39-LT-5055	Lordotic Ti Rod, 5.50 x 55mm	3	17	39-CC-0040	Cross Connector 40mm	2
6	39-LT-5060	Lordotic Ti Rod, 5.50 x 60mm	3	18	39-CC-0048	Cross Connector 48mm	2
7	39-LT-5065	Lordotic Ti Rod, 5.50 x 65mm	3	19	39-CC-0066	Cross Connector 66mm	2
8	39-LT-5070	Lordotic Ti Rod, 5.50 x 70mm	3	20	39-ST-5080	Straight Ti Rod, 5.50 x 80mm	3
9	39-LT-5075	Lordotic Ti Rod, 5.50 x 75mm	3	21	39-ST-5100	Straight Ti Rod, 5.50 x 100mm	3
10	39-LT-5080	Lordotic Ti Rod, 5.50 x 80mm	3	22	39-ST-5120	Straight Ti Rod, 5.50 x 120mm	3
11	39-LT-5090	Lordotic Ti Rod, 5.50 x 90mm	3	23	39-ST-5200	Straight Ti Rod, 5.50 x 200mm	3
12	39-LT-5100	Lordotic Ti Rod, 5.50 x 100mm	3	24	39-ST-5400	Straight Ti Rod, 5.50 x 400mm	3

REFORM® IMPLANT TRAY

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Bottom Level



#	Part No.	Description	Qty	#	Part No.	Description	Qty
1	39-PA-6530	6.5 x 30mm Polyaxial Pedicle Screw	6	28	39-PA-5530	5.5 x 30mm Polyaxial Pedicle Screw	6
2	39-PA-6535	6.5 x 35mm Polyaxial Pedicle Screw	6	29	39-PA-5535	5.5 x 35mm Polyaxial Pedicle Screw	6
3	39-PA-6540	6.5 x 40mm Polyaxial Pedicle Screw	10	30	39-PA-5540	5.5 x 40mm Polyaxial Pedicle Screw	8
4	39-PA-6545	6.5 x 45mm Polyaxial Pedicle Screw	10	31	39-PA-5545	5.5 x 45mm Polyaxial Pedicle Screw	8
5	39-PA-6550	6.5 x 50mm Polyaxial Pedicle Screw	8	32	39-PA-5550	5.5 x 50mm Polyaxial Pedicle Screw	6
6	39-PA-6555	6.5 x 55mm Polyaxial Pedicle Screw	8	33	39-RP-5530	Reduction Screw 5.5mm x 30mm	2
7	39-PA-7535	7.5 x 35mm Polyaxial Pedicle Screw	6	34	39-RP-5535	Reduction Screw 5.5mm x 35mm	4
8	39-PA-7540	7.5 x 40mm Polyaxial Pedicle Screw	8	35	39-RP-5540	Reduction Screw 5.5mm x 40mm	4
9	39-PA-7545	7.5 x 45mm Polyaxial Pedicle Screw	8	36	39-RP-5545	Reduction Screw 5.5mm x 45mm	4
10	39-PA-7550	7.5 x 50mm Polyaxial Pedicle Screw	6	37	39-RP-5550	Reduction Screw 5.5mm x 50mm	2
11	39-PA-7555	7.5 x 55mm Polyaxial Pedicle Screw	6	38	39-RP-6530	Reduction Screw 6.5mm x 30mm	2
12	39-PA-4525	4.5 x 25mm Polyaxial Pedicle Screw	2	39	39-RP-6535	Reduction Screw 6.5mm x 35mm	4
13	39-PA-4530	4.5 x 30mm Polyaxial Pedicle Screw	2	40	39-RP-6540	Reduction Screw 6.5mm x 40mm	4
14	39-PA-4535	4.5 x 35mm Polyaxial Pedicle Screw	2	41	39-RP-6545	Reduction Screw 6.5mm x 45mm	4
15	39-PA-4540	4.5 x 40mm Polyaxial Pedicle Screw	4	42	39-RP-6550	Reduction Screw 6.5mm x 50mm	2
16	39-PA-8545	8.5 x 45mm Polyaxial Pedicle Screw	4	43	39-RP-7535	Reduction Screw 7.5mm x 35mm	2
17	39-PA-8550	8.5 x 50mm Polyaxial Pedicle Screw	2	44	39-RP-7540	Reduction Screw 7.5mm x 40mm	2
18	39-PA-8555	8.5 x 55mm Polyaxial Pedicle Screw	2	45	39-RP-7545	Reduction Screw 7.5mm x 45mm	2
21	39-PA-8560	8.5 x 60mm Polyaxial Pedicle Screw	2	46	39-RP-7550	Reduction Screw 7.5mm x 50mm	2
22	39-PA-8570	8.5 x 70mm Polyaxial Pedicle Screw	2	47	39-RP-7555	Reduction Screw 7.5mm x 55mm	2
23	39-PA-8580	8.5 x 80mm Polyaxial Pedicle Screw	2	48	39-RP-8540	Reduction Screw 8.5mm x 40mm	2
24	39-PA-9560	9.5 x 60mm Polyaxial Pedicle Screw	2	49	39-RP-8545	Reduction Screw 8.5mm x 45mm	2
25	39-PA-9570	9.5 x 70mm Polyaxial Pedicle Screw	2	50	39-RP-8550	Reduction Screw 8.5mm x 50mm	2
26	39-PA-9580	9.5 x 80mm Polyaxial Pedicle Screw	2	51	39-RP-8555	Reduction Screw 8.5mm x 55mm	2
27	39-PA-5525	5.5 x 25mm Polyaxial Pedicle Screw	6				

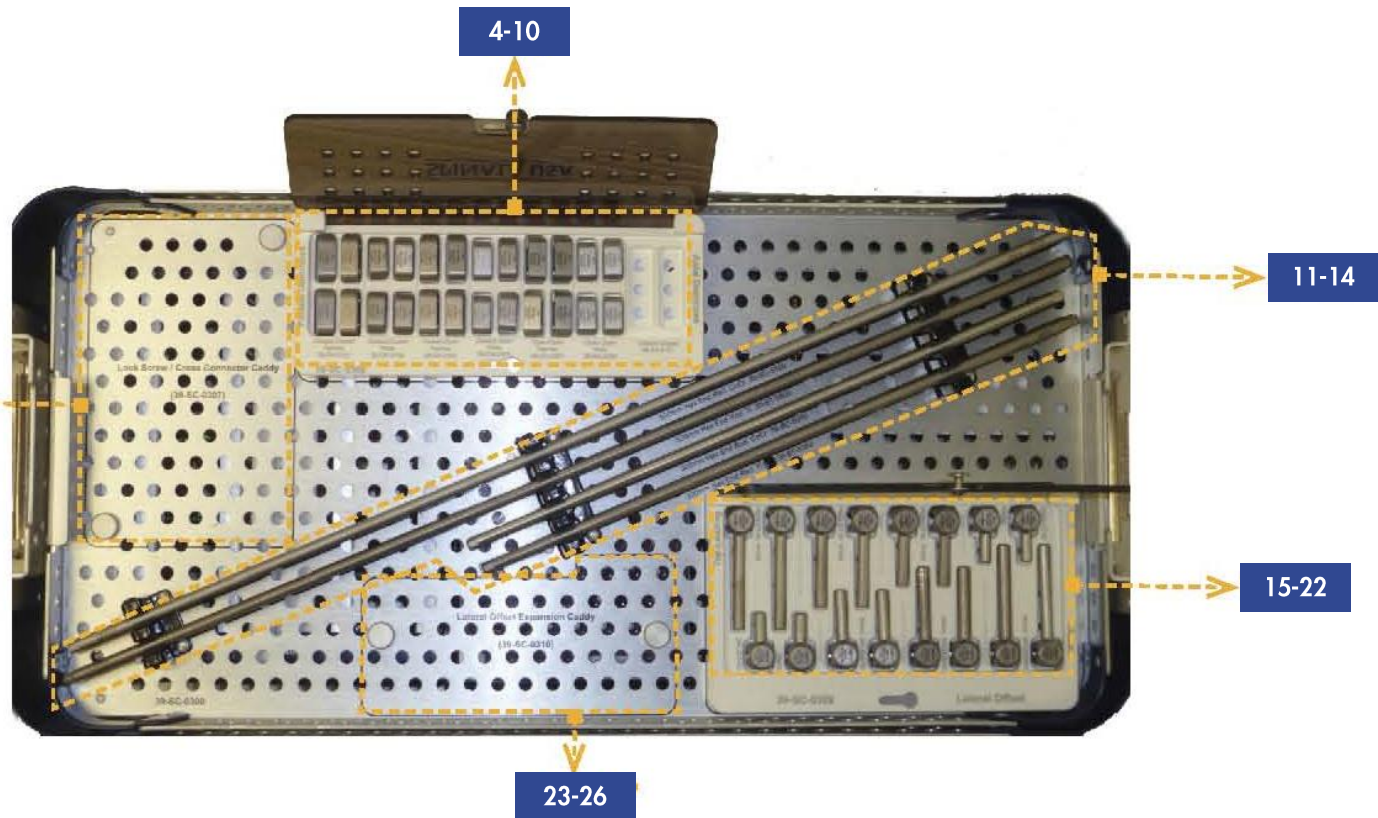
NOTE: Blue Type = Upon Request

- 1) Standard Set included: 5.5, 6.5 & 7.5mm Screws
- 2) Outlier Caddy (Special Request Only) includes: 4.5, 8.5 & 9.5mm Screws
- 3) Titanium included in Standard Set – Cobalt Chrome (Special Request Only)

REFORM® ADD-ON IMPLANT TRAY

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Top Level

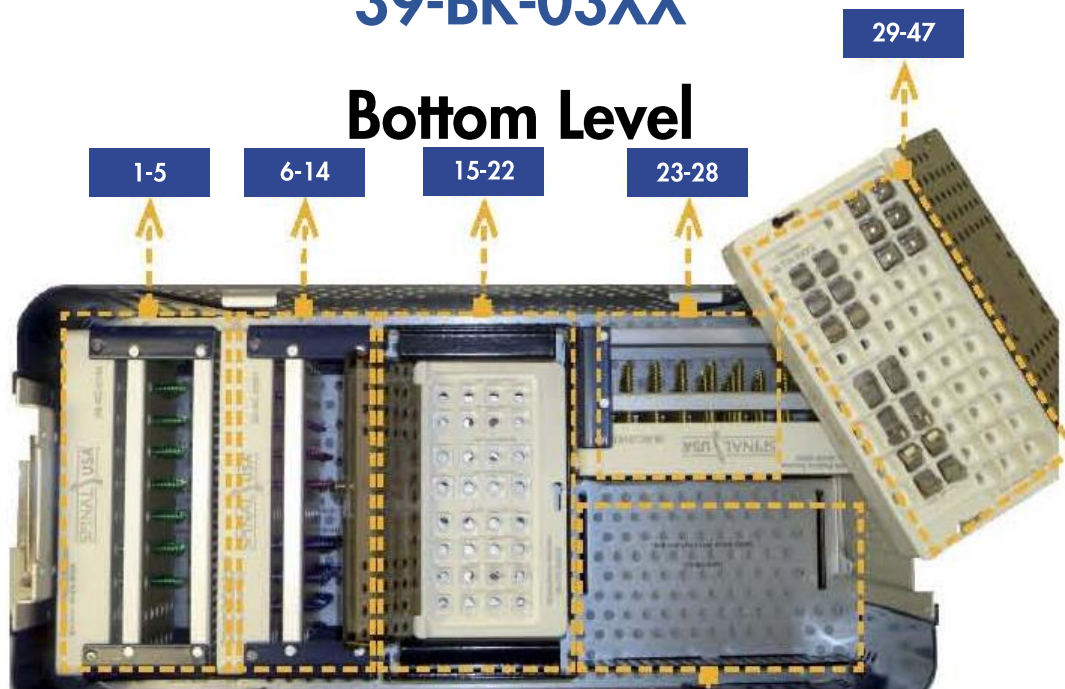


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1	39-LS-0100	Cap Screw / Lock-Screw	24	14	39-ST-5500	Straight Ti Rod, 5.50 x 500mm	3
2	39-CC-0030	Cross Connector 30mm	2	15	39-LO-0120	Lateral Offset, Closed 20mm	2
3	39-CC-0035	Cross Connector 35mm	2	16	39-LO-0130	Lateral Offset, Closed 30mm	2
4	39-DA-0101	Parallel Domino, Closed-Closed, Wide	4	17	39-LO-0140	Lateral Offset, Closed 40mm	2
5	39-DA-0102	Parallel Domino, Closed-Closed, Narrow	4	18	39-LO-0150	Lateral Offset, Closed 50mm	2
6	39-DA-0201	Parallel Domino, Closed-Open, Wide	4	19	39-LO-0220	Lateral Offset, Top-Loading 20mm	2
7	39-DA-0202	Parallel Domino, Closed-Open, Narrow	4	20	39-LO-0230	Lateral Offset, Top-Loading 30mm	2
8	39-DA-0301	Parallel Domino, Open-Open, Wide	4	21	39-LO-0240	Lateral Offset, Top-Loading 40mm	2
9	39-DA-0302	Parallel Domino, Open-Open, Narrow	4	22	39-LO-0250	Lateral Offset, Top-Loading 50mm	2
10	39-AA-0101	Axial Domino, Closed-Closed	2	23	39-LO-0220	Lateral Offset, Top-Loading 20mm	2
11	39-SC-5300	Straight CoCr Rod, 5.50 x 300mm	3	24	39-LO-0230	Lateral Offset, Top-Loading 30mm	2
12	39-SC-5500	Straight CoCr Rod, 5.50 x 500mm	3	25	39-LO-0240	Lateral Offset, Top-Loading 40mm	2
13	39-ST-5300	Straight Ti Rod, 5.50 x 300mm	3	26	39-LO-0250	Lateral Offset, Top-Loading 50mm	2

NOTE: Blue Type = Upon Request

REFORM® ADD-ON IMPLANT TRAY

39-BK-03XX



#	Part No.	Description	Qty
1	39-UP-6530	Uniplanar Screw - 6.5mm x 30mm	6
2	39-UP-6535	Uniplanar Screw - 6.5mm x 35mm	8
3	39-UP-6540	Uniplanar Screw - 6.5mm x 40mm	8
4	39-UP-6545	Uniplanar Screw - 6.5mm x 45mm	8
5	39-UP-6550	Uniplanar Screw - 6.5mm x 50mm	6
6	39-UP-4525	Uniplanar Screw - 4.5mm x 25mm	4
7	39-UP-4530	Uniplanar Screw - 4.5mm x 30mm	6
8	39-UP-4535	Uniplanar Screw - 4.5mm x 35mm	6
9	39-UP-4540	Uniplanar Screw - 4.5mm x 40mm	6
10	39-UP-4545	Uniplanar Screw - 4.5mm x 45mm	6
11	39-UP-7535	Uniplanar Screw - 7.5mm x 35mm	4
12	39-UP-7540	Uniplanar Screw - 7.5mm x 40mm	6
13	39-UP-7545	Uniplanar Screw - 7.5mm x 45mm	6
14	39-UP-7550	Uniplanar Screw - 7.5mm x 50mm	6
15	39-TH-0242	Straight Laminar Reduction Hook, MD	2
16	39-TH-0252	Ext-Body Laminar (+4mm) Reduction Hook, MD	2
17	39-TH-0262	Ramped Laminar Reduction Hook, MD	2
18	39-TH-0272	Down-Angled Laminar Reduction Hook, MD	2
19	39-TH-0351	Offset Angled Reduction Hook, MD, Right	2
20	39-TH-0352	Offset Angled Reduction Hook, MD, Left	2
21	39-TH-0451	Angled Reduction Hook, MD, Right	2
22	39-TH-0452	Angled Reduction Hook, MD, Left	2
23	39-UP-5525	Uniplanar Screw - 5.5mm x 25mm	4
24	39-UP-5530	Uniplanar Screw - 5.5mm x 30mm	6
25	39-UP-5535	Uniplanar Screw - 5.5mm x 35mm	6
26	39-UP-5540	Uniplanar Screw - 5.5mm x 40mm	6

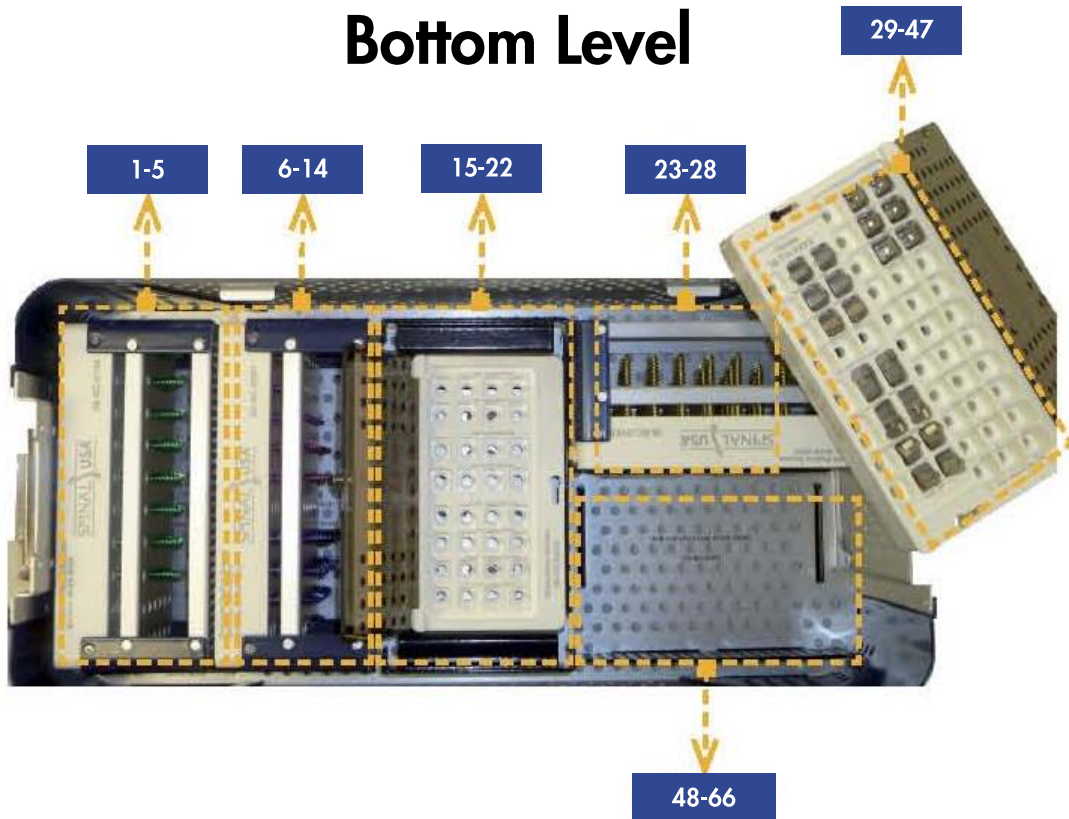
#	Part No.	Description	Qty
27	39-UP-5545	Uniplanar Screw - 5.5mm x 45mm	6
28	39-UP-5550	Uniplanar Screw - 5.5mm x 50mm	6
29	39-TH-0101	Pedicle Hook, SM	2
30	39-TH-0102	Pedicle Hook, MD	2
31	39-TH-0103	Pedicle Hook, LG	2
32	39-TH-0201	Straight Laminar Hook, SM, Narrow	2
33	39-TH-0202	Straight Laminar Hook, SM, Wide	2
34	39-TH-0203	Straight Laminar Hook, MD, Narrow	2
35	39-TH-0204	Straight Laminar Hook, MD, Wide	2
36	39-TH-0205	Straight Laminar Hook, LG, Narrow	2
37	39-TH-0206	Straight Laminar Hook, LG, Wide	2
38	39-TH-0212	Ext-Body (+4mm) Laminar Hook, MD	2
39	39-TH-0213	Ext-Body (+4mm) Laminar Hook, LG	2
40	39-TH-0221	Ramped Laminar Hook, SM	2
41	39-TH-0222	Ramped Laminar Hook, MD	2
42	39-TH-0232	Down-Angled Laminar Hook, MD	2
43	39-TH-0233	Down-Angled Laminar, LG	2
44	39-TH-0301	Offset Angled Hook, MD, Right	2
45	39-TH-0302	Offset Angled Hook, MD, Left	2
46	39-TH-0401	Angled Hook, MD, Right	2
47	39-TH-0402	Angled Hook, MD, Left	2
48	39-RP-5530	Reduction Poly Screw 5.5mm x 30mm	2
49	39-RP-5535	Reduction Poly Screw 5.5mm x 35mm	4

NOTE: Blue Type = Upon Request

Continued on next page

REFORM® ADD-ON IMPLANT TRAY 39-BK-03XX (Cont'd..)

Bottom Level



#	Part No.	Description	Qty
50	39-RP-5540	Reduction Polyaxial Screw 5.5mm x 40mm	4
51	39-RP-5545	Reduction Polyaxial Screw 5.5mm x 45mm	4
52	39-RP-5550	Reduction Polyaxial Screw 5.5mm x 50mm	2
53	39-RP-6530	Reduction Polyaxial Screw 6.5mm x 30mm	2
54	39-RP-6535	Reduction Polyaxial Screw 6.5mm x 35mm	4
55	39-RP-6540	Reduction Polyaxial Screw 6.5mm x 40mm	4
56	39-RP-6545	Reduction Polyaxial Screw 6.5mm x 45mm	4
57	39-RP-6550	Reduction Polyaxial Screw 6.5mm x 50mm	2
58	39-RP-7535	Reduction Polyaxial Screw 7.5mm x 35mm	2
59	39-RP-7540	Reduction Polyaxial Screw 7.5mm x 40mm	2
60	39-RP-7545	Reduction Polyaxial Screw 7.5mm x 45mm	2
61	39-RP-7550	Reduction Polyaxial Screw 7.5mm x 50mm	2
62	39-RP-7555	Reduction Polyaxial Screw 7.5mm x 55mm	2
63	39-RP-8540	Reduction Polyaxial Screw 8.5mm x 40mm	2
64	39-RP-8545	Reduction Polyaxial Screw 8.5mm x 45mm	2
65	39-RP-8550	Reduction Polyaxial Screw 8.5mm x 50mm	2
66	39-RP-8555	Reduction Polyaxial Screw 8.5mm x 55mm	2

Reduction Uniplanar Screws (Sent Separately, Not in a Caddy)

Part No.	Description	Qty
39-RU-5525	Reduction Uniplanar Screw Assembly - 5.5mm x 25mm	3
39-RU-5530	Reduction Uniplanar Screw Assembly - 5.5mm x 30mm	3
39-RU-5535	Reduction Uniplanar Screw Assembly - 5.5mm x 35mm	6
39-RU-5540	Reduction Uniplanar Screw Assembly - 5.5mm x 40mm	6
39-RU-5545	Reduction Uniplanar Screw Assembly - 5.5mm x 45mm	6
39-RU-5550	Reduction Uniplanar Screw Assembly - 5.5mm x 50mm	3
39-RU-6530	Reduction Uniplanar Screw Assembly - 6.5mm x 30mm	3
39-RU-6535	Reduction Uniplanar Screw Assembly - 6.5mm x 35mm	6
39-RU-6540	Reduction Uniplanar Screw Assembly - 6.5mm x 40mm	6
39-RU-6545	Reduction Uniplanar Screw Assembly - 6.5mm x 45mm	6
39-RU-6550	Reduction Uniplanar Screw Assembly - 6.5mm x 50mm	3
39-RU-7535	Reduction Uniplanar Screw Assembly - 7.5mm x 35mm	3
39-RU-7540	Reduction Uniplanar Screw Assembly - 7.5mm x 40mm	3
39-RU-7545	Reduction Uniplanar Screw Assembly - 7.5mm x 45mm	3
39-RU-7550	Reduction Uniplanar Screw Assembly - 7.5mm x 50mm	3

NOTE: Blue Type = Upon Request

REFORM® HA IMPLANT CASE 39-BK-0601



Part #	Description	Qty.
39-PH-5535	Reform Ø5.5 x 35mm Polyaxial Pedicle Screw	6
39-PH-5540	Reform Ø5.5 x 40mm Polyaxial Pedicle Screw	6
39-PH-5545	Reform Ø5.5 x 45mm Polyaxial Pedicle Screw	6
39-PH-5550	Reform Ø5.5 x 50mm Polyaxial Pedicle Screw	6
39-PH-6530	Reform Ø6.5 x 30mm Polyaxial Pedicle Screw	6
39-PH-6535	Reform Ø6.5 x 35mm Polyaxial Pedicle Screw	6
39-PH-6540	Reform Ø6.5 x 40mm Polyaxial Pedicle Screw	10
39-PH-6545	Reform Ø6.5 x 45mm Polyaxial Pedicle Screw	10
39-PH-6550	Reform Ø6.5 x 50mm Polyaxial Pedicle Screw	8
39-PH-6555	Reform Ø6.5 x 55mm Polyaxial Pedicle Screw	6
39-PH-7535	Reform Ø7.5 x 35mm Polyaxial Pedicle Screw	6
39-PH-7540	Reform Ø7.5 x 40mm Polyaxial Pedicle Screw	6
39-PH-7545	Reform Ø7.5 x 45mm Polyaxial Pedicle Screw	6
39-PH-7550	Reform Ø7.5 x 50mm Polyaxial Pedicle Screw	6
39-PH-7555	Reform Ø7.5 x 55mm Polyaxial Pedicle Screw	6

REFORM® INSTRUMENT TRAY

39-BK-0201

Top Level



#	Part No.	Description	Qty
1	39-CH-0004	Ratcheting In-Line "Straight" Handle, 1/4" SQ	2
2	39-SP-0545	Pedicle Screw Tap Assembly 4.5mm - (Tap is .5mm undersized)	1
3	39-SP-0555	Pedicle Screw Tap Assembly 5.5mm - (Tap is .5mm undersized)	1
4	39-SP-0565	Pedicle Screw Tap Assembly 6.5mm - (Tap is .5mm undersized)	1
5	39-SP-0575	Pedicle Screw Tap Assembly 7.5mm - (Tap is .5mm undersized)	1
6	39-SP-0585	Pedicle Screw Tap Assembly 8.5mm - (Tap is .5mm undersized)	1
7	39-SP-0595	Pedicle Screw Tap Assembly 9.5mm - (Tap is .5mm undersized)	1
8	39-SP-0011	Ball Tip Sounder Straight	2
9	39-SP-0007	Straight Pedicle Probe	1
10	39-SP-0005	Duckbill Pedicle Probe	1
11	39-SP-0003	Curved Pedicle Probe	1
12	39-SP-0001	Bone Awl	1
13	39-CH-0003	Ratcheting T-Handle, 1/4" SQ	2

REFORM® INSTRUMENT TRAY

39-BK-0201

Middle Level



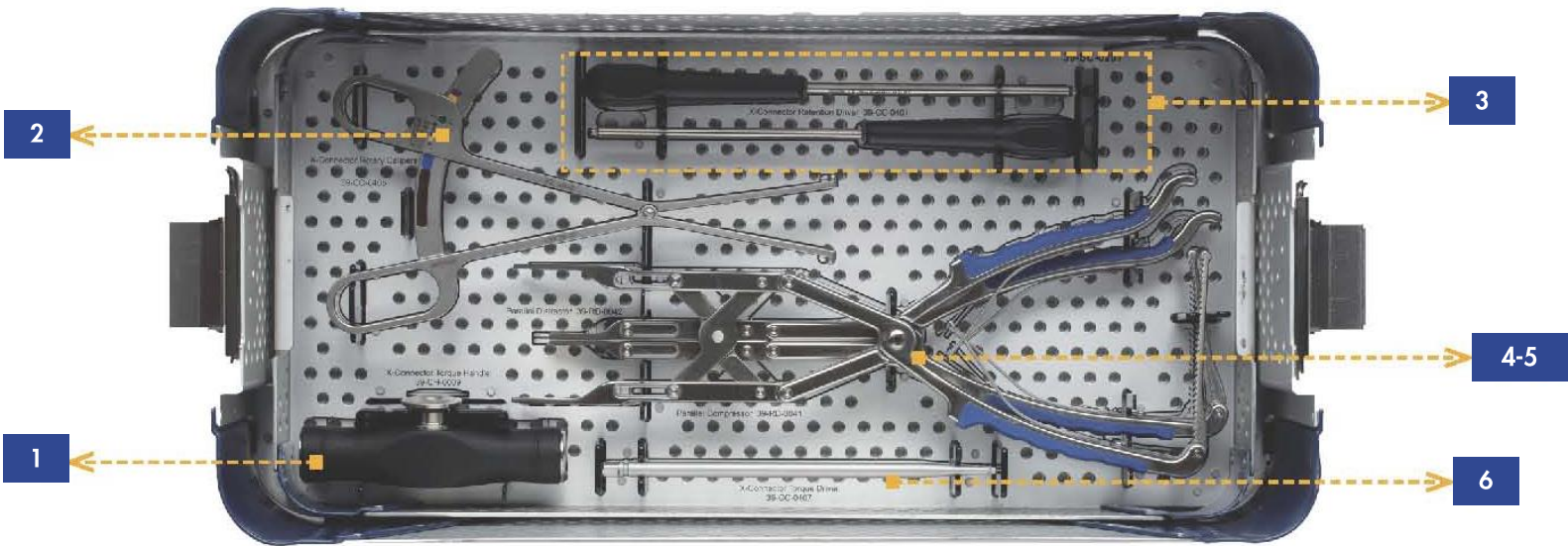
#	Part No.	Description	Qty
1	39-RD-0010	Flexible Rod Template – 200mm	1
2	39-RD-0011	Flexible Rod Template – 400mm	1
3	39-RD-0061	Counter-Torque Wrench	1
4	39-RD-0060	Lock-Screw Torque Driver	2
5	39-SP-0603	Dual-Side Lock-Screw Driver	2
6	39-SP-0815	Rod Pusher 5.5mm	1
7	39-SP-0800	Tulip Manipulator	1
8	39-SP-0601	Retention Bone-Screw Driver	2
9	39-SP-0730	Polyaxial Driver	2
10	39-SP-0805	Rod Inserter Forceps – 5.5mm	1
11	39-SP-0825	Lateral Tulip Holder	1
12	39-RD-0070	Extended Tap Removal Tool*	1
13	39-CH-0008	Offset Ratcheting Torque Handle	1

*Only included with Reduction Screws

REFORM[®] INSTRUMENT TRAY

39-BK-0201

Bottom Level

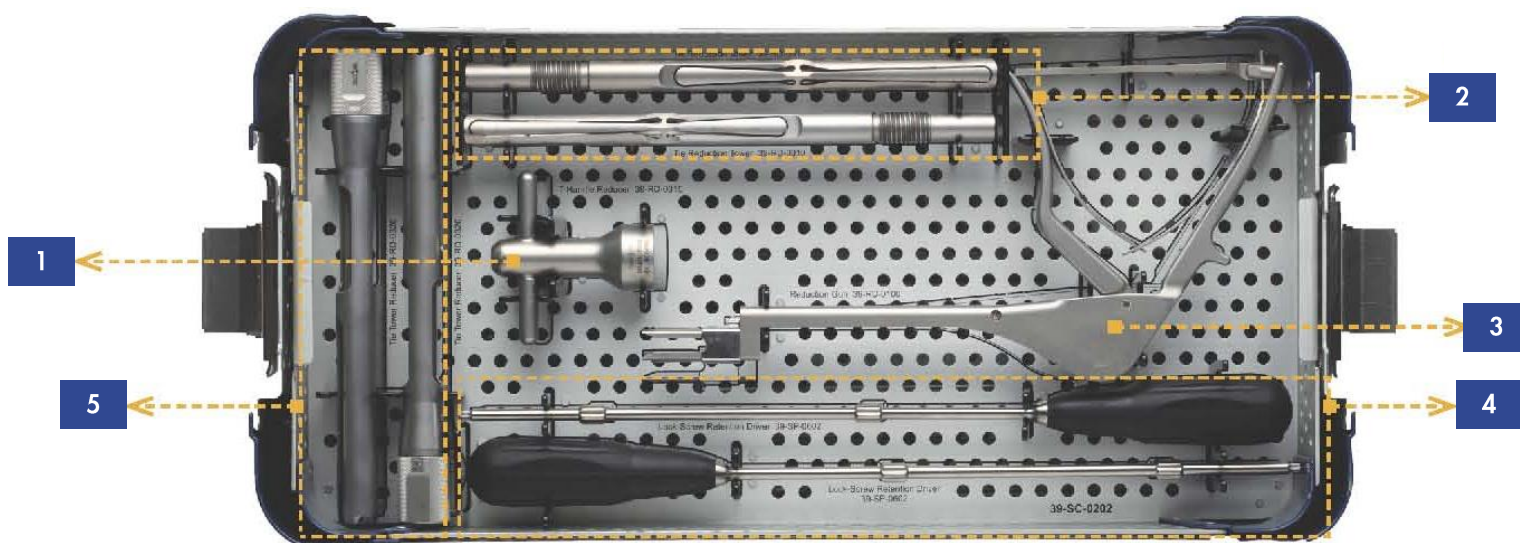


#	Part No.	Description	Qty
1	39-CH-0009	X-Connector Torque Handle	1
2	39-CC-0405	X-Connector Rotary Calipers	1
3	39-CC-0401	X-Connector Retention Driver (Self-Retaining)	2
4	39-RD-0041	Parallel Compressor	1
5	39-RD-0042	Parallel Distractor	1
6	39-CC-0407	X-Connector Torque Driver	1

REFORM® INSTRUMENT TRAY

39-BK-0202

Top Level



#	Part No.	Description	Qty
1	39-RD-0315	T-Handle Reducer	1
2	39-RD-0310	Tie Reduction Tower	2
3	39-RD-0100	Reduction Gun	1
4	39-RD-0602	Lock-Screw Retention Driver	2
5	39-SP-0320	Tie Tower Reducer (capable of 25mm reduction)	2

REFORM® INSTRUMENT TRAY

39-BK-0202

Bottom Level



#	Part No.	Description	Qty
1	39-RD-0001	French Rod Bender - 5.5mm	1
2	39-RD-0020	In Situ Rod Bender – (Left)	1
3	39-RD-0021	In Situ Rod Bender – (Right)	1
4	39-SP-0810	Rod Gripper - 5.5mm	1
5	39-RD-0201	Rod Rocker	1

REFORM® ADD-ON INSTRUMENT TRAY 39-BK-0203

Top Level



#	Part No.	Description	Qty
1	39-RD-0316	T-Handle Reducer	1
2	39-RD-0348	Tower Bridge Hex Wrench	1
3	39-RD-0310	Tie Reduction Tower	6
4	39-RD-0320	Tie Tower Reducer	6
5	39-RD-0344	Tower Connectors	8
6	39-RD-0345	Tower Thumbscrew	8

REFORM® ADD-ON INSTRUMENT TRAY

39-BK-0203

Middle Level



#	Part No.	Description	Qty
1	39-RD-0012	Flexible Rod Template - 500mm	1
2	39-RD-0032	Coronal Rod Bender Bridge	1
3	39-RD-0030	Coronal Rod Bender - (Left)	1
4	39-RD-0031	Coronal Rod Bender - (Right)	1
5	39-RD-0346	Tower Bridge, Single	2
6	39-RD-0347	Tower Bridge, Double	2
7	39-SP-0810	Rod Gripper - 5.5mm	1

REFORM® ADD-ON INSTRUMENT TRAY

39-BK-0203

Bottom Level

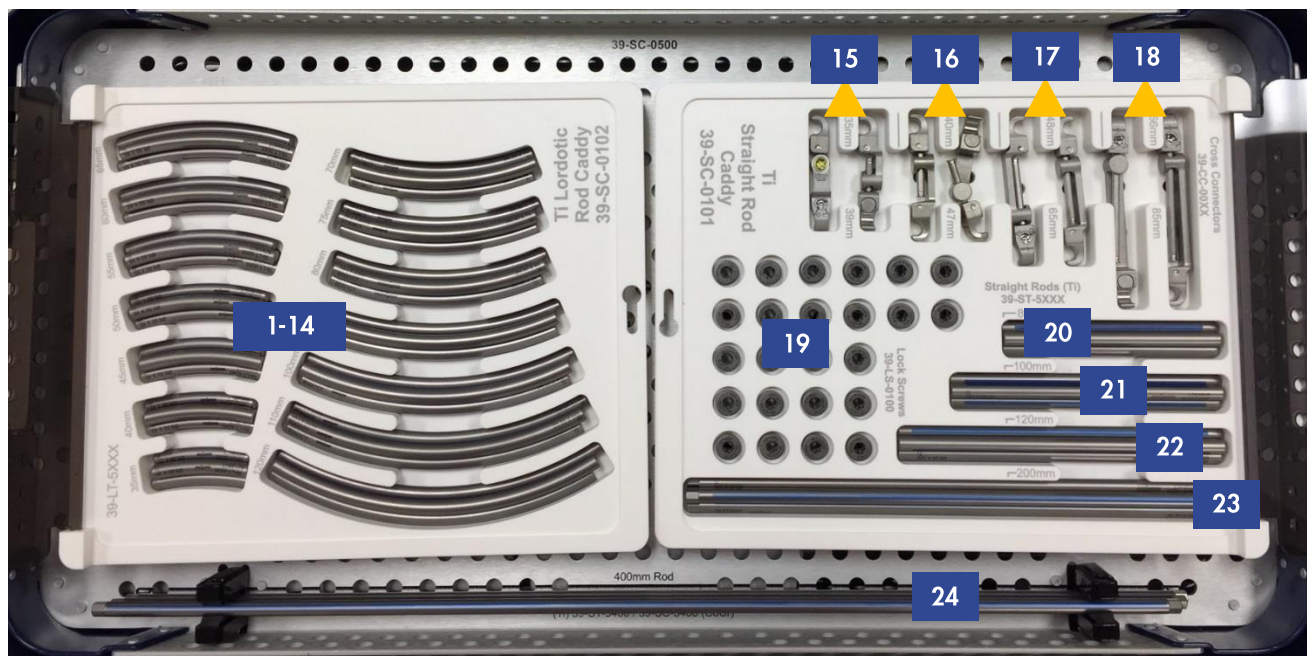


#	Part No.	Description	Qty
1	39-RD-0550	Superior Hook Holder	1
2	39-RD-0570	Domino Inserter/Counter-Torque	1
3	39-RD-0050	Rod De-Rotation Hex Wrench	1
4	39-RD-0502	Laminar Elevator, Medium	1
5	39-RD-0503	Laminar Elevator, Small	1
6	39-RD-0500	Pedicular Elevator	1
7	39-RD-0560	Hook Pusher	1

REFORM® MODULAR IMPLANT TRAY

39-BK-051X

Top Level



#	Part No.	Description	Qty	#	Part No.	Description	Qty
1	39-LT-5035	Lordotic Rod, Ti - \varnothing 5.5mm x 35mm	3	13	39-LT-5110	Lordotic Rod, Ti - \varnothing 5.5mm x 110mm	3
2	39-LT-5040	Lordotic Rod, Ti - \varnothing 5.5mm x 40mm	3	14	39-LT-5120	Lordotic Rod, Ti - \varnothing 5.5mm x 120mm	3
3	39-LT-5045	Lordotic Rod, Ti - \varnothing 5.5mm x 45mm	3	15	39-CC-0035	35mm - Cross-Connector	2
4	39-LT-5050	Lordotic Rod, Ti - \varnothing 5.5mm x 50mm	3	16	39-CC-0040	40mm - Cross-Connector	2
5	39-LT-5055	Lordotic Rod, Ti - \varnothing 5.5mm x 55mm	3	17	39-CC-0048	48mm - Cross-Connector	2
6	39-LT-5060	Lordotic Rod, Ti - \varnothing 5.5mm x 60mm	3	18	39-CC-0066	66mm - Cross-Connector	2
7	39-LT-5065	Lordotic Rod, Ti - \varnothing 5.5mm x 65mm	3	19	39-LS-0100	Lock Screw	24
8	39-LT-5070	Lordotic Rod, Ti - \varnothing 5.5mm x 70mm	3	20	39-ST-5080	Straight Rod, Ti - \varnothing 5.5mm x 80mm	3
9	39-LT-5075	Lordotic Rod, Ti - \varnothing 5.5mm x 75mm	3	21	39-ST-5100	Straight Rod, Ti - \varnothing 5.5mm x 100mm	3
10	39-LT-5080	Lordotic Rod, Ti - \varnothing 5.5mm x 80mm	3	22	39-ST-5120	Straight Rod, Ti - \varnothing 5.5mm x 120mm	3
11	39-LT-5090	Lordotic Rod, Ti - \varnothing 5.5mm x 90mm	3	23	39-ST-5200	Straight Rod, Ti - \varnothing 5.5mm x 200mm	3
12	39-LT-5100	Lordotic Rod, Ti - \varnothing 5.5mm x 100mm	3	24	39-ST-5400	Straight Rod, Ti - \varnothing 5.5mm x 400mm	3

REFORM® MODULAR IMPLANT TRAY

39-BK-051X

Bottom Level



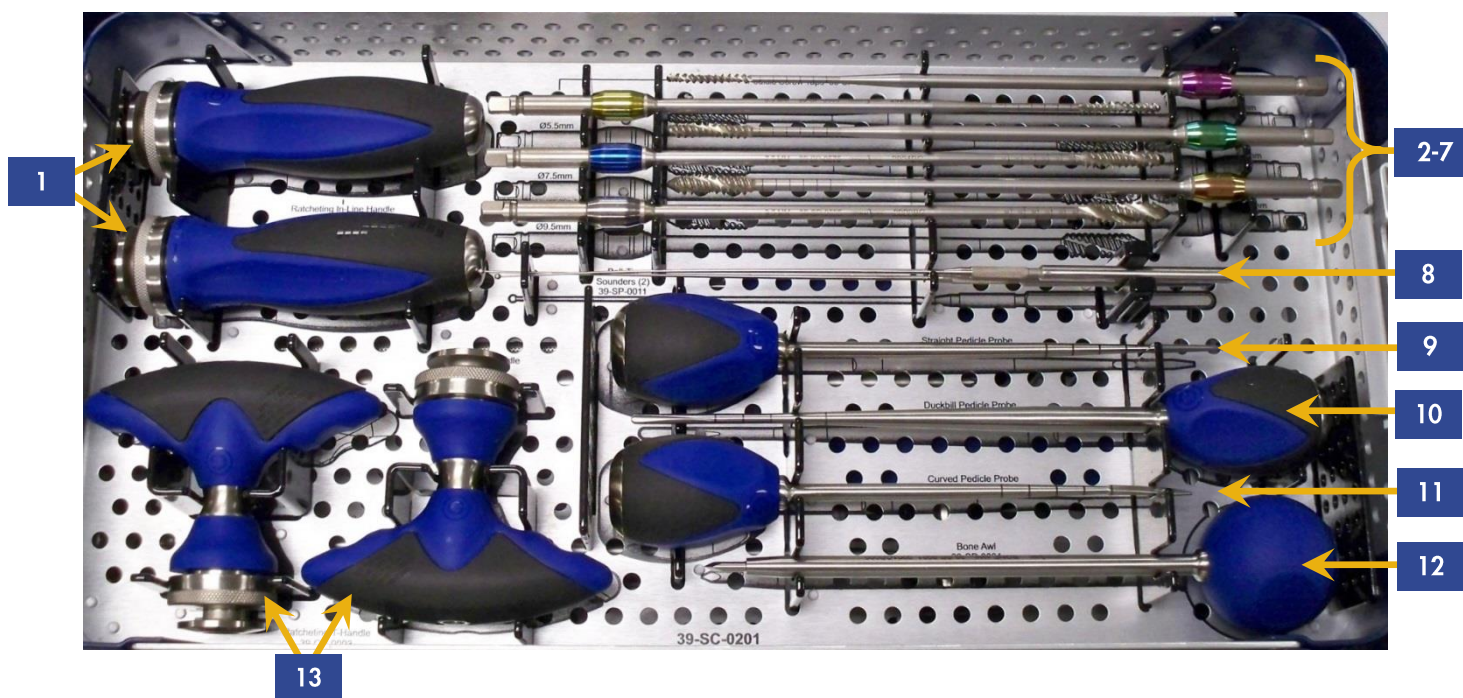
#	Part No.	Description	Qty	#	Part No.	Description	Qty
1	39-MS-5530	Bone Screw - ϕ 5.5mm x 30mm	6	18	39-MT-0302	Reduction Tulip Assembly	10
2	39-MS-5535	Bone Screw - ϕ 5.5mm x 35mm	6	19	39-MS-4525	Bone Screw - ϕ 4.5mm x 25mm	2
3	39-MS-5540	Bone Screw - ϕ 5.5mm x 40mm	8	20	39-MS-4530	Bone Screw - ϕ 4.5mm x 30mm	2
4	39-MS-5545	Bone Screw - ϕ 5.5mm x 45mm	8	21	39-MS-4535	Bone Screw - ϕ 4.5mm x 35mm	2
5	39-MS-5550	Bone Screw - ϕ 5.5mm x 50mm	6	22	39-MS-4540	Bone Screw - ϕ 4.5mm x 40mm	4
6	39-MS-6530	Bone Screw - ϕ 6.5mm x 30mm	6	23	39-MS-4545	Bone Screw - ϕ 4.5mm x 45mm	4
7	39-MS-6535	Bone Screw - ϕ 6.5mm x 35mm	6	24	39-MS-8540	Bone Screw - ϕ 8.5mm x 40mm	4
8	39-MS-6540	Bone Screw - ϕ 6.5mm x 40mm	10	25	39-MS-8545	Bone Screw - ϕ 8.5mm x 45mm	4
9	39-MS-6545	Bone Screw - ϕ 6.5mm x 45mm	10	26	39-MS-8550	Bone Screw - ϕ 8.5mm x 50mm	2
10	39-MS-6550	Bone Screw - ϕ 6.5mm x 50mm	8	27	39-MS-8555	Bone Screw - ϕ 8.5mm x 55mm	2
11	39-MS-6555	Bone Screw - ϕ 6.5mm x 55mm	8	28	39-MS-8560	Bone Screw - ϕ 8.5mm x 60mm	2
12	39-MS-7535	Bone Screw - ϕ 7.5mm x 35mm	6	29	39-MS-8570	Bone Screw - ϕ 8.5mm x 70mm	2
13	39-MS-7540	Bone Screw - ϕ 7.5mm x 40mm	8	30	39-MS-8580	Bone Screw - ϕ 8.5mm x 80mm	2
14	39-MS-7545	Bone Screw - ϕ 7.5mm x 45mm	8	31	39-MS-9560	Bone Screw - ϕ 9.5mm x 60mm	2
15	39-MS-7550	Bone Screw - ϕ 7.5mm x 50mm	6	32	39-MS-9570	Bone Screw - ϕ 9.5mm x 70mm	2
17	39-MT-0301	Standard Tulip Assembly	25	33	39-MS-9580	Bone Screw - ϕ 9.5mm x 80mm	2

- 1) Standard Set included: 5.5, 6.5 & 7.5mm Screws
- 2) Outlier Caddy (Special Request Only) includes: 4.5, 8.5 & 9.5mm Screws
- 3) Titanium included in Standard Set - Cobalt Chrome (Special Request Only)

NOTE: Blue Type = Upon Request

REFORM® MODULAR INSTRUMENT TRAY 39-BK-0501

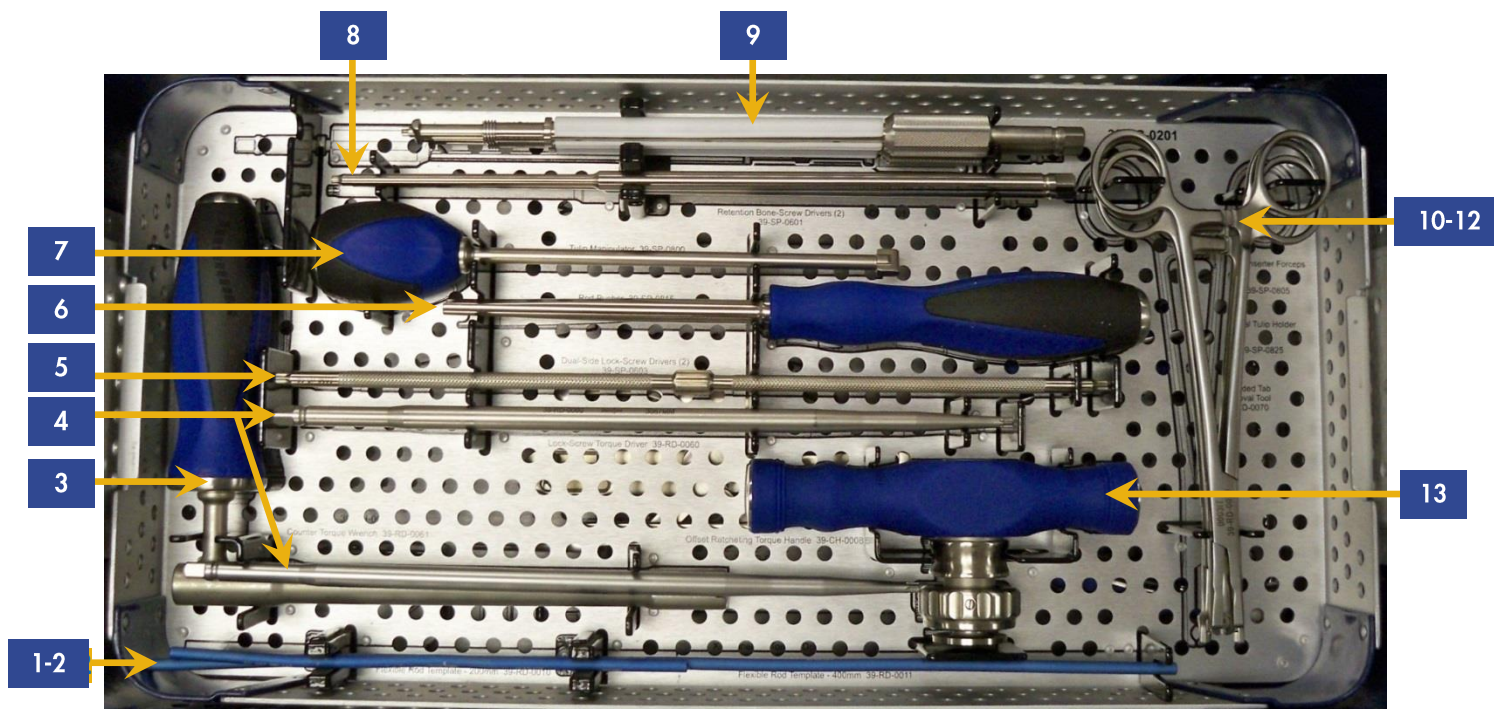
Top Level



#	Part No.	Description	Qty
1	39-CH-0004	Ratcheting In-Line "Straight" Handle, 1/4" SQ	2
2	39-SP-0545	Pedicle Screw Tap Assembly 4.5mm - (Tap is .5mm undersized)	1
3	39-SP-0555	Pedicle Screw Tap Assembly 5.5mm - (Tap is .5mm undersized)	1
4	39-SP-0565	Pedicle Screw Tap Assembly 6.5mm - (Tap is .5mm undersized)	1
5	39-SP-0575	Pedicle Screw Tap Assembly 7.5mm - (Tap is .5mm undersized)	1
6	39-SP-0585	Pedicle Screw Tap Assembly 8.5mm - (Tap is .5mm undersized)	1
7	39-SP-0595	Pedicle Screw Tap Assembly 9.5mm - (Tap is .5mm undersized)	1
8	39-SP-0011	Ball Tip Sounder Straight	2
9	39-SP-0007	Straight Pedicle Probe	1
10	39-SP-0005	Duckbill Pedicle Probe	1
11	39-SP-0003	Curved Pedicle Probe	1
12	39-SP-0001	Bone Awl	1
13	39-CH-0003	Ratcheting T-Handle, 1/4" SQ	2

REFORM® MODULAR INSTRUMENT TRAY 39-BK-0501

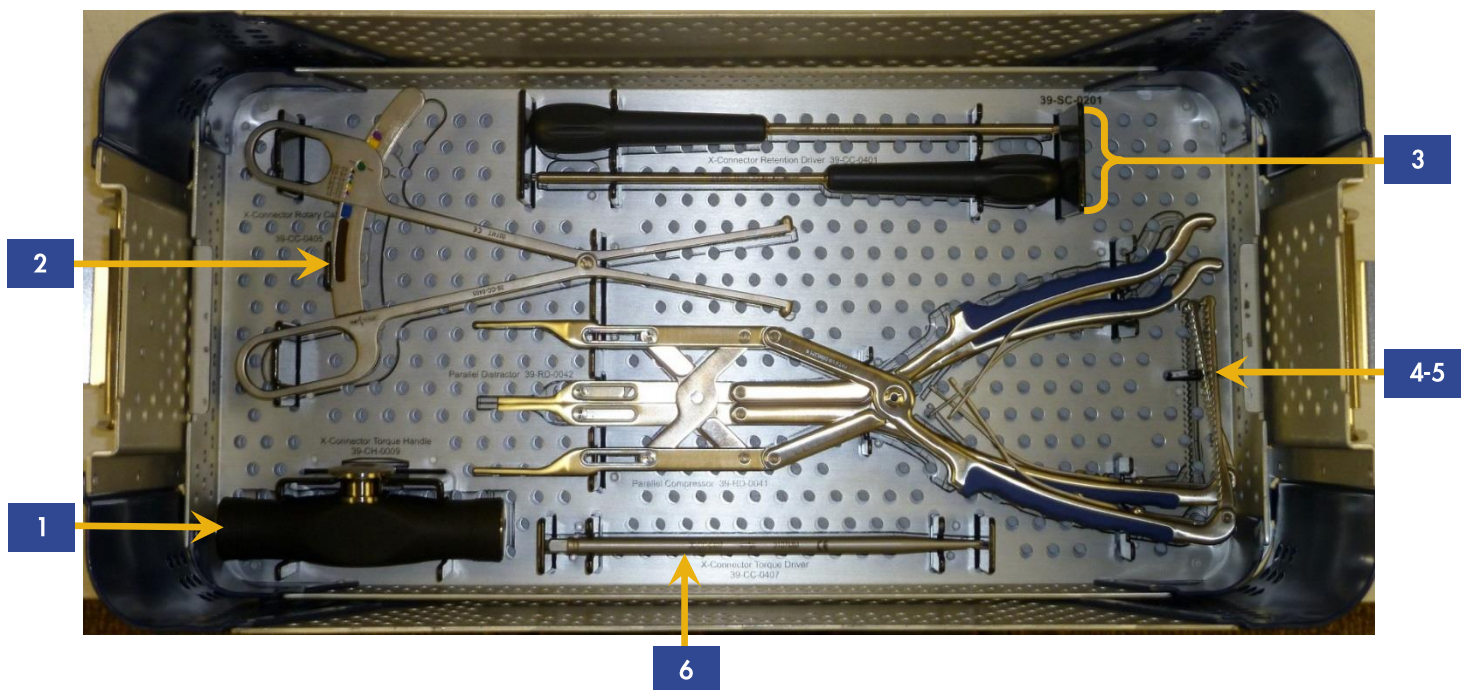
Middle Level



#	Part No.	Description	Qty
1	39-RD-0010	Flexible Rod Template - 200mm	1
2	39-RD-0011	Flexible Rod Template - 400mm	1
3	39-RD-0061	Counter-Torque Wrench	1
4	39-RD-0060	Lock-Screw Torque Driver	2
5	39-SP-0603	Dual-Side Lock-Screw Driver	2
6	39-SP-0815	Rod Pusher 5.5mm	1
7	39-SP-0800	Tulip Manipulator	1
8	39-SP-0601	Retention Bone-Screw Driver	2
9	39-SP-0730	Polyaxial Driver	2
10	39-SP-0805	Rod Inserter Forceps - 5.5mm	1
11	39-SP-0825	Lateral Tulip Holder	1
12	39-RD-0070	Extended-Tab Removal Tool (Only Included with the Reduction Screws)	1
13	39-CH-0008	Offset Ratcheting Torque Handle	1

REFORM® MODULAR INSTRUMENT TRAY 39-BK-0501

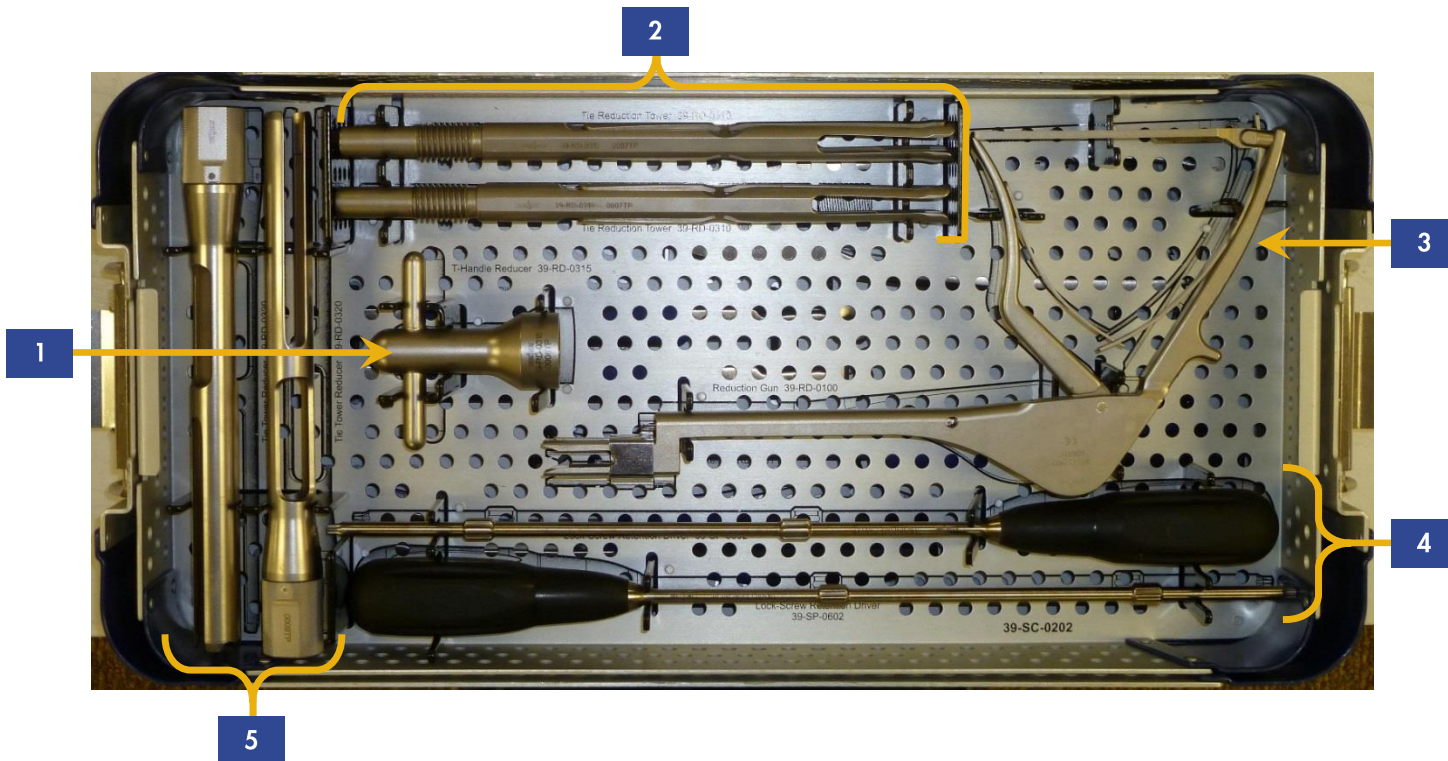
Bottom Level



#	Part No.	Description	Qty
1	39-CH-0009	X-Connector Torque Handle	1
2	39-CC-0405	X-Connector Rotary Calipers	1
3	39-CC-0401	X-Connector Retention Driver (Self-Retaining)	2
4	39-RD-0041	Parallel Compressor	1
5	39-RD-0042	Parallel Distractor	1
6	39-CC-0407	X-Connector Torque Driver	1

REFORM® MODULAR INSTRUMENT TRAY 39-BK-0502

Top Level



#	Part No.	Description	Qty
1	39-RD-0315	T-Handle Reducer	1
2	39-RD-0310	Tie Reduction Tower	2
3	39-RD-0100	Reduction Gun	1
4	39-SP-0602	Lock-Screw Retention Driver	2
5	39-RD-0320	Tie Tower Reducer (Capable of 2" Reduction)	2

REFORM® MODULAR INSTRUMENT TRAY 39-BK-0502

Bottom Level



#	Part No.	Description	Qty
1	39-RD-0001	French Rod Bender - 5.5mm	1
2	39-RD-0020	In Situ Rod Bender - (Left)	1
3	39-RD-0021	In Situ Rod Bender - (Right)	1
4	39-SP-0810	Rod Gripper - 5.5mm	1
5	39-RD-0201	Rod Rocker	1

SURGICAL TECHNIQUE

1

PREOPERATIVE PLANNING

The Surgeon should consider for surgery only those patients indicated for the use of the Reform® Pedicle Screw System. The Surgeon should have a complete understanding of the surgical technique and of the system's design rationale, indications, contraindications and applications. The Surgeon should have a complete understanding of the function and limitations of each implant and instrument in the system.

2

PEDICLE PREPARATION

- Locate the desired entry point in the pedicle and perforate the cortex with the Awl (39-SP-0001) (Figure 1).
- Use a Straight (39-SP-0007), Curved (39-SP-0003), or Duckbill (39-SP-0005) Probe to open the pedicle canal (Figure 2). A pathway and trajectory through the pedicle can be established with a Probe allowing the instrument to follow the path of least resistance. The Probe should contact bone at all times. If resistance is felt while creating a pathway through the pedicle the entry point and trajectory should be re-evaluated. Laser etching on the Probe will indicate the depth of the Probe within the canal (30mm, 40mm, 50mm, 60mm, and 70mm depths).
- The prepared pathway can be explored with the Ball Tip Sounder (39-SP-0011) to confirm that integrity of the pedicle wall has not been violated (Figure 3).
- The appropriate Tap may be used to prepare the pedicle for Screw insertion (Figure 4). The Tap sizes are undersized and correspond to the diameter of the Screw and are laser etched. Taps can be utilized with the Ratcheting In-line Handle (39-CH-0004) or the Ratcheting T-Handle (39-CH-0003). If using the Reform HA Coated Pedicle Screw System, the appropriate tap is used to prepare the pedicle for screw insertion. The tap sizes are undersized and correspond to the diameter of the screw (5.5mm, 6.5mm, 7.5mm and 8.5mm). Tap only to the depth of the tap thread.
- Repeat the preparation procedure for each pedicle that has been identified for instrumentation.

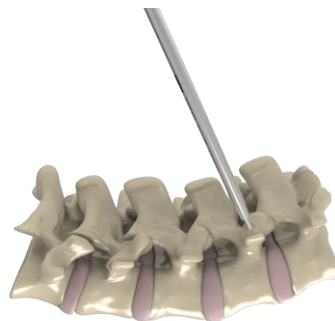


Figure 1

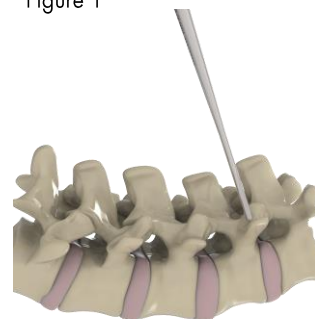


Figure 2

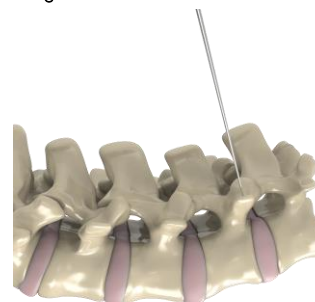


Figure 3

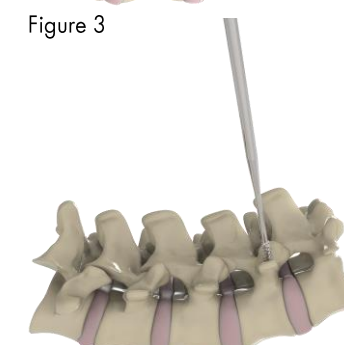


Figure 4

SURGICAL TECHNIQUE (continued)

3

POLYAXIAL SCREW INSERTION

- a. With the pedicle pathway prepared and appropriate Screw length and diameter determined, the Polyaxial Screw is loaded for insertion on the preferred Screw Driver Assembly.
- b. The Polyaxial Driver (39-SP-0730) is attached to either the Ratcheting Inline Handle, (39-CH-0004) or Ratcheting T-Handle (39-CH-0003) (not shown).
 - i. Depress the silver collate on the Inline Handle or T-Handle and insert the Polyaxial Driver male end into the female end of the Handle. Confirm that the Driver is fully seated in the appropriate Handle and will not disengage.
- c. The Polyaxial Screw is now attached to the preferred Screw Driver Assembly.
 - i. Load the appropriate Screw chosen for length and diameter onto the hexalobe tip portion of the Polyaxial Driver. The Polyaxial Screw should be fully seated on the Driver assembly before the Screw Head Locking Sleeve of the Driver is engaged (Figure 5).
 - ii. With the Screw held firmly seated on the Driver, thread the Screw Head Locking Sleeve clockwise until fully engaged and flush with the convex portion of the Driver.
 - iii. Advance the locking coupler until it is flush with the base of the screw driver locking sleeve. Ensure that the coupler clicks into position (Figure 6). The Screw Driver will not disengage from the screw while the locking coupler is in this position.
- d. The Polyaxial Screw is now inserted into the pedicle (Figures 7 and 7a).
- e. Disengage the Polyaxial Driver by disengaging the locking coupler and turning the shaft counterclockwise.
- f. Repeat the procedure for Polyaxial Screw insertion in each pedicle identified for instrumentation.



Figure 5

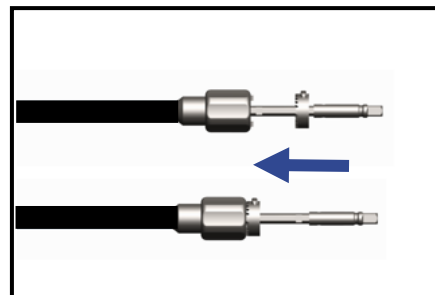


Figure 6

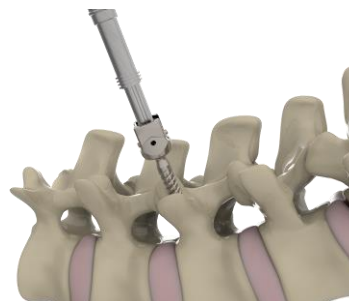


Figure 7

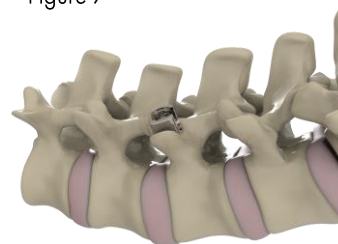


Figure 7a

SURGICAL TECHNIQUE (continued)

4

MODULAR SCREW INSERTION

- a. With the pedicle pathway prepared and Screw length and diameter determined, the appropriate Screw is loaded for insertion on the Screw Driver Assembly.
- b. The Modular Screw Driver (39-MD-0700) is attached to either the Ratcheting Inline Handle, (39-CH-0004) or Ratcheting T-Handle (39-CH-0003).
 - i. Depress the silver collate on the Inline Handle or T-Handle and insert the Modular Screw Driver male end into the female end of the Handle (Figure 7b). Confirm that the Driver is fully seated in the appropriate Handle and will not disengage.
- c. The Modular Screw is now attached to the Screw Driver Assembly.
 - i. Load the appropriate Modular Screw chosen for length and diameter by placing the head of the Screw into the collet of the Screw Driver's distal tip. Turn the knob clockwise until the sleeve completely surrounds the collet (Figure 7c).
- d. The Modular Screw is now inserted into the pedicle (Figure 7d).
- e. Disengage the Driver by turning the Screw Driver Knob counterclockwise.
- f. Repeat the procedure for Modular Screw insertion in each pedicle identified for instrumentation.



Figure 7b

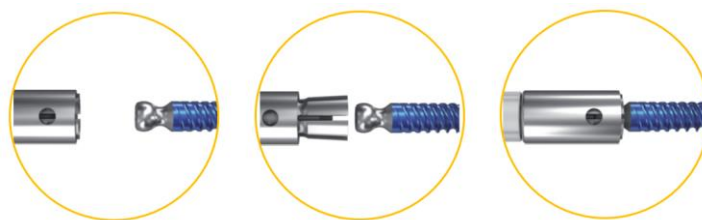


Figure 7c



Figure 7d

SURGICAL TECHNIQUE (continued)

5

DECORTICATION

Place the bone Planar (39-MD-0100) over the head of the Modular Screw and rotate the Planar clockwise and counterclockwise to decorticate the bone and allow for optimal seating of the Modular Tulip (Figure 7e).

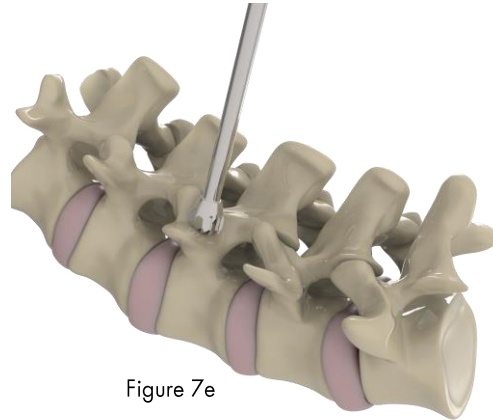


Figure 7e

6

MODULAR TULIP ATTACHMENT

Attach the appropriate Modular Tulip using either the Lateral Tulip Clamp (39-SP-0825) or the Angled Lateral Tulip Clamp (39-MD-0825) by aligning the Tulip Clamp with the tabs of the Modular Tulip. Slide the Tulip over the Bone Screw and apply an axial force until an audible click is heard (Figure 7f). Upward pressure of the attached Lateral Tulip Clamp can be applied to ensure that the Tulip is properly inserted.

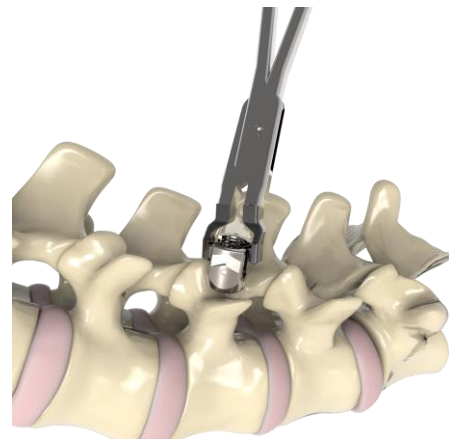


Figure 7f

SURGICAL TECHNIQUE (continued)

7

HOOK SURGICAL PROCEDURE

There are four possible Hook placement sites in the spine: pedicle, transverse process, supra-lamina and infra-lamina.

The surgeon must choose the appropriate Hook based on the individual patient's anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants.

The first site is the pedicle. Pedicle Hooks (39-TH-010X) are placed in the thoracic spine via the facet joint (Figure 8). The direction for the Pedicle Hooks is always cephalad.

The facet of the appropriate level is identified and the capsule is removed. The cartilage on the inferior articular process of the next distal level should be visualized.

The facet is entered with the Pedicle Elevator (39-RD-0500).

The Pedicle Hook is inserted with the Superior Hook Holder (39-RD-0550) (Figure 8) and seated flush against the facet and the pedicle.

The second site is the transverse process. The Angled Hook (39-TH-040X) is recommended for this site.

An Elevator is used to dissect around the superior surface of the transverse process and then the Angled Hook is placed in the required position.



Figure 8

SURGICAL TECHNIQUE (continued)

7

HOOK SURGICAL PROCEDURE (cont.)

The third possible site is the superior lamina. The Down Angled Laminar (39-TH-023X), Straight Laminar (39-TH-020X), Straight Laminar Ext. Body (+4mm) (39-TH-021X), Ramped Laminar (39-TH-022X) or Offset Angled Laminar (39-TH-030X) are recommended for this site. The direction is always caudal. These Hooks may be combined with other Hooks to produce a claw construct.

The ligamentum flavum is divided in the midline and excised. The amount of bone removed from the lamina may vary depending on the size of the Hook blade and throat angle chosen.

The inferior edge of the next proximal lamina is removed to permit the intracanal placement of the Hook.

The appropriate Lamina Hook is then placed by using the Hook Pusher (39-RD-0560) until well seated against the lamina.

The fourth possible site is the inferior lamina. The Down Angled Laminar, Straight Laminar, Ext.-Body Laminar (+4mm), Ramped Laminar or Offset Angled Laminar are recommended for this site in the lumbar spine. The direction is always cephalad.

Similar to the Supra-Lamina step, the ligamentum flavum is divided in the midline and excised. The inferior edge of the selected lamina is removed to permit intra-canal placement of the Hook.

The appropriate Hook is then placed using the Hook Pusher until well seated against the lamina.



Pedicule Hook



Wide



Narrow

Straight Laminar Hooks



Ext.-Body Laminar (+4mm) Hook



Ramped Laminar Hook



Down Angled Laminar Hook



Angled Hook - Right



Left



Right

Offset Angled Laminar Hooks



Straight Laminar Reduction Hook



Ext.-Body Laminar (+4mm) Reduction



Ramped Laminar Reduction Hook



Down Angled Laminar Reduction Hook



Offset Angled Laminar Reduction Hook - Right



Angled Reduction Hook - Right

8

REDUCTION HOOK SURGICAL PROCEDURE

The Reform® Reduction Hooks are designed to further complement the innovative design of the existing Reform Hook range. These Hooks help to address, correct and also stabilize difficult anatomic variations. The Reduction Hooks are designed with removable tabs that allow the surgeon to approximate the spine to the desired sagittal or axial profile.

They are provided in 6 styles similar to the standard Reform Hooks:

1. Straight Laminar (39-TH-0242)
2. Straight Laminar Ext.
3. Body (+4mm) (39-TH-0252)
4. Ramped Laminar (39-TH-0262)
5. Down Angled Laminar (39-TH-0272)
6. Offset Angled Laminar (39-TH-0351; 39-TH-0352) and Angled Laminar (39-TH-0451; 39-TH-0452).

Reduction Hooks are most commonly placed at the apex of the concavity. Contour the Rod to match the required spinal contours in the sagittal plane (Figure 9).

Utilize each Reduction Hook in the same way as the standard Reform Hooks. Place the contoured Rod into the spine anchors and fully seat. The extended tabs of the Reduction Hooks provide a means of capturing a Rod that may have crossed the midline and would otherwise be out of reach of the anchor (Figure 10).

Once the correction procedures have been carried out and the spine is in a satisfactory position, the definitive tightening of the Locking Cap (39-LS-0100) can be completed with the Offset Ratcheting Torque Handle (39-CH-0008), Counter-Torque Wrench (39-RD-0061), and Locking Cap Torque Driver (39-RD-0060). The extended tabs of the Reduction Hook can then be removed by using the Extended Tab Removal Tool (39-RD-0070) (Figure 11).

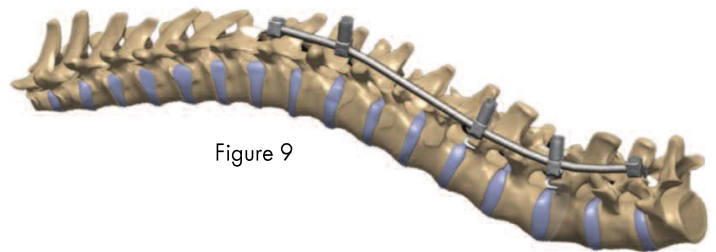


Figure 9

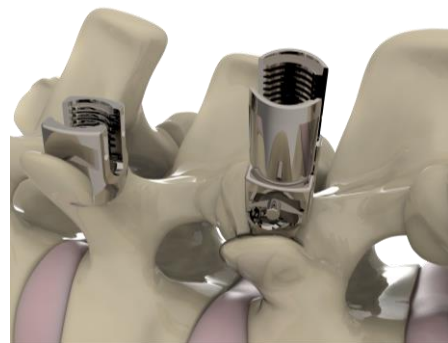


Figure 10

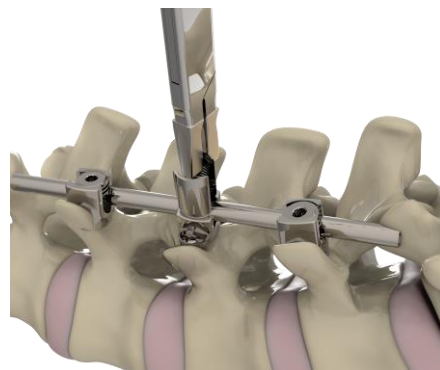


Figure 11

SURGICAL TECHNIQUE (continued)

9

ROD INSERTION

- a. Once all Screws and Hooks have been inserted, the appropriate Straight Rod or Curved Rod may be applied. A Flexible Rod Template (39-RD-0012) or Rotary Caliper (39-CC-0405) may be used to measure the appropriate length Rod. (Figure 12)
- b. Use the appropriate pre-cut Rod or cut a longer Rod using a rod cutter (rod cutter not provided).
- c. The Polyaxial Screw design will allow for some lateral Screw offset.
- d. The Rod can be contoured if desired utilizing the French Rod Bender (39-RD-0001). Note: Repeated bending can weaken the Rod.
- e. Once the appropriate Rod has been selected, use the Rod Holding Forceps (39-SP-0805) to facilitate insertion into the Screw Head Tulip (Figure 13).
- f. A Tulip Manipulator (39-SP-0800) may be used to align the Polyaxial Screws Head.

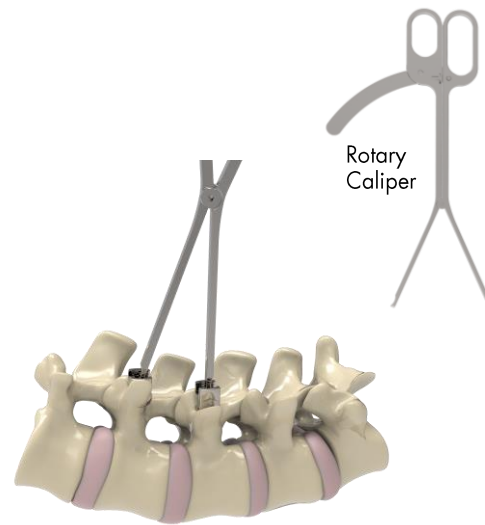


Figure 12

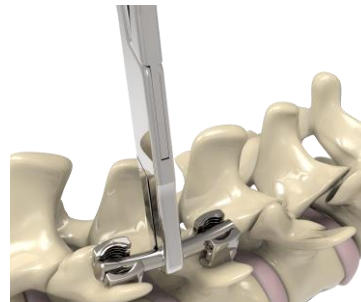


Figure 13

SURGICAL TECHNIQUE (continued)

10

ROD REDUCTION

The Rod must be seated in the Reform® Screw head in order to engage the Locking Cap (39-LS-0100) for tightening. There are three alternative instruments used for this process.

Option 1

The Rod Pusher (39-SP-0815) can be used to seat the Rod. For constructs with two or more levels, begin with the central Screw. (Figure 14) Proceed to Step 11, Locking Cap Insertion.

Option 2

The Rod Rocker (39-RD-0201) can be utilized to seat the Rod within the Screw head (Figure 15). The Rod Rocker easily slides into the lateral slots on the side of the Screw head and is rotated backwards. This levers the Rod into the head of the implant.

NOTE:

Placing the Rod Rocker on the side where the Rod is higher may be more effective at getting the Rod seated evenly in the implant (Figure 16).

Proceed to Step 11, Locking Cap Insertion.

Option 3

The Tie Reduction Tower (39-RD-0310) is used when additional force is needed to seat the Rod into the Screw head. Engage the Tie Reduction Tower on the Screw head with the slots on the Tie Reduction Tower aligned with the rod slot on the Screw head (Figure 17). Place the Tower Reducer (39-RD-0320) over the Tie Reduction Tower and turn the capture sleeve clockwise to reduce the Rod into the Screw head. The T-Handle Reducer (39-RD-0315) can be used if additional force is required (Figure 18). Once the Rod is fully seated, the Locking Cap (39-LS-0100) can be seated using the Locking Cap Retention Driver (39-SP-0602) (Figure 19). Proceed to vertebral Body Derotation Procedure for advanced techniques.

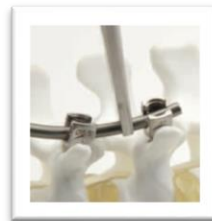


Figure 14



Figure 15

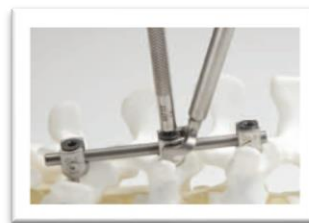


Figure 16



Figure 17



Figure 18



Figure 19

SURGICAL TECHNIQUE (continued)

11

LOCKING CAP INSERTION

For Options 1 & 2 – Once the Rod is fully seated, the Locking Cap (39-LS-0100) can be inserted into the Screw head with the Dual Sided Locking Cap Driver (39-SP-0603).

12

FINAL TIGHTENING

Once the correction procedures have been carried out and the spine is in a satisfactory position, the final tightening of the Locking Cap can be commenced. Load the square end of the Locking Cap Torque Driver (39-RD-0060) into the Torque Wrench Handle. Place the Counter Torque Wrench (39-RD-0061) over the Reform Screw Head and apply downward pressure to stabilize the Screw Head and Rod. Turn the Torque Wrench Handle clockwise 90° and an audible click is heard (Figure 20).



Figure 20

ADDITIONAL TECHNIQUES

1

DOMINO SURGICAL PROCEDURE

Seven Domino Rod-to-Rod Connectors are offered in the Reform System (Figure 1). Two styles are available in the Closed-Closed Dominoes: a Wide style (39-DA-0101) and a Narrow style (39-DA-0102).

Two styles are available in the Closed-Open Dominoes: a Wide style (39-DA-0201) and a Narrow style (39-DA-0202).

Two styles are available in the Open-Open Dominoes: a Wide style (39-DA-0301) and a Narrow style (39-DA-0302).

There is also an inline, axial connector in a Closed-Closed style (39-AA-0101).

The narrow style accommodates parallel Rods that are 8.5mm apart.

The wide style accommodates parallel rods that are 11mm apart.

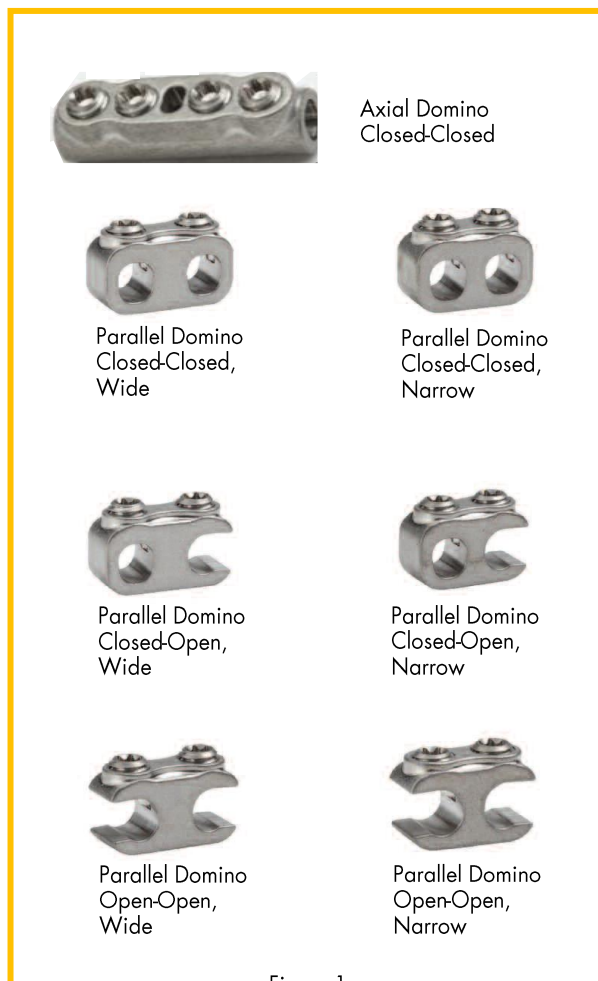
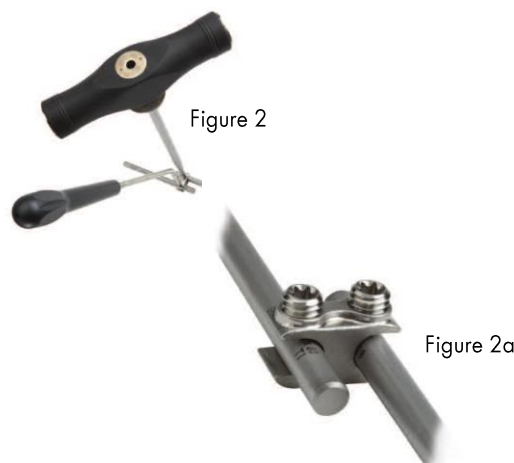


Figure 1

Place the appropriate style Domino onto the Longitudinal Rods utilizing the Domino Inserter (39-RD-0570) or the Self-retaining T20 Driver (39-CC-0401). The Self-retaining T20 Driver should be used for preliminary tightening of the preassembled Domino Set Screws (39-LS-0200). Once the desired position of the Domino on the Longitudinal Rods has been achieved, the Torque-Limiting T20 Driver (39-CC-0407) and the Torque-Limiting Handle (39-CH-0009) should be used for final tightening of the Set Screw to 66 in-lbs. The Domino Inserter (39-RD-0570) can be used as a counter-torque device to stabilize the construct during final tightening (Figure 2 and 2a).



ADDITIONAL TECHNIQUES

2

LATERAL OFFSET PROCEDURE

Eight Lateral Offset designs are offered in the Reform Application. Two styles are available in the Lateral Offsets: a Top Loading Offset connection (39-LO-02XX) and a Closed-Head connection (39-LO-01XX). Both styles come in lengths of 20, 30, 40, and 50mm.

All Lateral Offset Connectors will be perpendicular to the Rod when attached (Figure 3).



Figure 3

Preload the Lateral Offset onto the Longitudinal Rod. The post of the Lateral offset may be cut and contoured as deemed necessary. A Lateral Offset may also be used at points along the construct to connect to a screw that may be Lateral and out of line with the pedicle screw above and below this point.

When tightening the locking screws, first secure the locking screws along the Longitudinal Rod. Then secure each locking screw where it mates with the post of the Lateral Offset within the Lateral Screw. Finally, tighten each locking screw at the Lateral Offset/Longitudinal Rod interface using the Offset Ratcheting Torque Handle and Torque Driver (39-CH-008 & 39-RD-0060), and Counter Torque Wrench (39-RD-0061) (Figure 4). The locking torque for the Lateral Offset locking screw is 106in-lbs.



Figure 4

ADDITIONAL TECHNIQUES

3

CROSS-CONNECTOR SURGICAL PROCEDURE

Cross-Connectors can be added to increase the torsional stability of a construct. Long constructs may require Cross-Connectors to be placed at proximal and distal ends of the construct to increase rigidity. The Rotary Calipers can be used to determine the proper length of the Cross-Connector (Figure 5).

Two Self-Retaining T20 Drivers (39-CC-0401) are provided to engage and retain the Cross-Connector cams during placement (Figure 6). The midline screw should be loosened to allow for multi-axial flexibility when seating the Cross-Connector onto the constructs.

Once each hook portion of the Cross-Connector is fully seated on the Rod, the Self-Retaining T20 Drivers may each be rotated 90° clockwise to fully engage the Cross-Connector cam to the Rod.

Next, the midline nut is definitively tightened using the Torque-Limiting T20 Driver (39-CC-0407). An audible click from the Torque-Limiting T20 Driver will confirm that the midline nut is adequately tightened (Figure 7).



Figure 5



Figure 6



Figure 7

CROSS-CONNECTOR REMOVAL

If removal of a Cross-Connector is necessary, place the Torque-Limiting Screwdriver over the midline nut and turn counterclockwise to loosen.

Place the Self-Retaining T20 Driver into each Cam and turn 90° counterclockwise to loosen from the Rods.

ADVANCED TECHNIQUE

1

VERTEBRAL BODY DEROTATION PROCEDURE

Reduction maneuvers can be performed to manipulate and stabilize deformities of the thoracolumbar spine through the use of segmental anchors and specialized instrumentation. Multiple anchors provide increased rigidity while allowing for safe and consistent correction.

Reduction can be achieved by bringing the spine to meet the Rod (as in the case of translation maneuvers) or by simply pushing the Rod to meet the spine to capture the Rod for fixation (cantilever maneuver). With flexible deformities, locking the proximal and distal ends of the construct (neutral levels) and segmentally reducing can result in translation of the spine. Anterior releases or osteotomies may be for correction of more rigid curves.



Figure 1

MULTIPLE LEVEL SPINAL DEROTATION

In order to complete a multiple level derotation technique, the Tie Reduction Towers (39-RD-0310) are connected to apical screw heads on both concave and convex sides once the concave Rod is in place. If applicable the Tie Tower Reducers (39-RD-0320) may be attached to the Tie Reduction Towers to facilitate Rod reduction. The Tower Connector (39-RD-0344) can be attached to the proximal portion of the Tie Reduction Towers. The Tower Connectors can be aligned to the Tower Bridge, Single (39-RD-0346) or Tower Bridge, Double (39-RD-0347) to aid with rotation. The Tower Connectors are secured to the Tower Bridges via the Tower Thumbscrews (39-RD-0345) (Figure 1).

At this point, the derotation maneuver can be performed to bring the spine into alignment (Figures 2 & 3).

After reduction is completed, proceed to locking cap insertion.

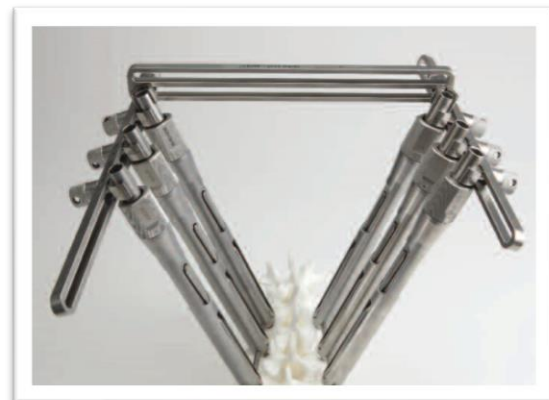


Figure 2



Figure 3

ADVANCED TECHNIQUE

1

VERTEBRAL BODY DEROTATION PROCEDURE (cont.)

INDIVIDUAL LEVEL SPINAL DEROTATION

Individual level spinal derotation can be done as the sole derotation maneuver or in addition to the multiple level maneuver described on the previous page. Implant both Rods and capture them with the Locking Caps.

Most Locking Caps should be left loose since lengthening of the spine is expected at each level that will be segmentally derotated. Only the Set Screws in the distal neutral vertebra should be tightened.

The Tie Reduction Towers are connected to the affected proximal vertebrae. If applicable, the Tie Tower Reducers (39-RD-0320) may be attached to the Tie Reduction Towers to facilitate rod reduction. The Tower Connector (39-RD-0344) can be attached to the proximal portion of the Tie Reduction Towers.

The Tower Connectors can be aligned to the Tower Bridge, Single (39-RD-0346) or Tower Bridge, Double (39-RD-0347) to aid with derotation. The Tower Connectors are secured to the Tower Bridges via the Tower Thumbscrews (39-RD-0345).

At this point, the derotation maneuver can be performed to bring the spine into alignment (Figure 4). Derotate each proximal vertebral body to achieve a neutral position in reference to the neutral distal vertebra. After derotation of each segment, the set screws are tightened. Repeat this process, moving along towards the apex.



Figure 4

OPTIONAL SURGICAL PROCEDURES

Removal of the Reform® Pedicle Screw System components is performed by reversing the order of the implant procedure.

NOTE:

The Counter-Torque Wrench (39-RD-0061) should be used when removing screws to prevent unintended screw pullout. The Counter-Torque Wrench may be used either directly on the screw to be removed, or on the adjacent screws, to hold the construct in place during removal.

REFORM KITS

Reform® Implants Kits

Part No.	Description	Part No.	Description
39-BK-0101	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws w/ Ti Rods	39-BK-0105	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws w/ CC Rods
39-BK-0102	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Outlier Screws (4.5, 8.5 & 9.5MM) & Ti Rods	39-BK-0106	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Outlier Screws (4.5, 8.5 & 9.5MM) & CC Rods
39-BK-0103	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Reduction Screws & Ti Rods	39-BK-0107	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Reduction Screws & CC Rods
39-BK-0104	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Outlier Screws (4.5, 8.5 & 9.5MM), Reduction Screws & Ti Rods	39-BK-0108	Implant Kit Std 5.5, 6.5 & 7.5mm Polyaxial Screws, Outlier Screws (4.5, 8.5 & 9.5MM), Reduction Screws & CC Rods

Reform Instrument Kits

Part No.	Description	Part No.	Description
39-BK-0201	Instrument Kit 1	39-BK-0202	Instrument Kit 2

Reform Add-On Deformity Implant Kits

Part No.	Description	Part No.	Description
39-BK-0301	Add-On Implant Kit Std Polyaxial Screws	39-BK-0305	Uniplanar Screws
39-BK-0302	Add-On Implant Kit Std Polyaxial Screws & Hooks	39-BK-0306	Uniplanar Screws & Hooks
39-BK-0303	Add-On Implant Kit Std Polyaxial Screws & Reduction Screws	39-BK-0307	Uniplanar Screws & Reduction Screws
39-BK-0304	Add-On Implant Kit Std Polyaxial Screws, Reduction Screws & Hooks	39-BK-0308	Uniplanar Screws, Reduction Screws & Hooks

Reform Add-On Instrument Kit

Part No.	Description
39-BK-0203	Deformity Add-On Instrument Kit

CONTRAINDICATIONS, POTENTIAL ADVERSE EFFECTS & WARNINGS

CONTRAINDICATIONS

The Reform® Pedicle Screw System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device

POTENTIAL ADVERSE EFFECTS

All possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any or all of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or decrease in spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS

The following are warnings for this device.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only. AN IMPLANT SHOULD NEVER BE RE-USED. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of pedicle screw system should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight patient, activity level, other patient conditions, etc. which may impact on the performance of the system.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. The Reform HA Coated Pedicle Screws are provided sterile. Therefore, cleaning and sterilization are not required. Prior to use, check product packaging for damage, and the expiration date. If found damaged or expired, please contact the manufacturer. All other components of the Reform HA Coated Pedicle Screw system are supplied clean and non-sterile and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the validated cycle parameters Instructions for Use (IFU) (LBL-IFU-021).
14. Titanium components should not be used with stainless steel components within the same system.
15. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
16. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.



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